From: Clarke, Victoria
To: Ross, Margaret; Lowit, Anna
Subject: 2018 Annual Report
Date: Tuesday, June 11, 2019 3:52:00 PM

Hi Margaret,
Anna and I touched base about her 278. She's resubmitted the 2018 278 back to us (there's no transaction to report because previously owned stock increased above the reporting threshold), so I think we're all set.

Victoria
Victoria Clarke
Attorney-Advisor
U.S. Environmental Protection Agency
Office of General Counsel
Washington, D.C. |7348 WJCN
EPA Office: 202-564-1149
EPA Cell: 202-336-9101

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 09 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Recusal and Screening Arrangement

FROM: Anna B. Lowit, Ph.D.
Senior Science Advisor

TO: Richard Keigwin, Director and Deputy Ethics Official
Office of Pesticides Programs

This memorandum provides you with written notification of my obligation to recuse from certain matters in which I have a financial interest, or a personal or business relationship. Because of the current level of my financial ownership, I am disqualified from participating personally and substantially in any particular matter that affects the following entities as specific parties:

RECUSAL LIST – SPECIFIC PARTY MATTERS	
(b) (6)	(b) (6)

In addition, I am disqualified from participating personally and substantially in any particular matter of general applicability that is focused on the interests of any individual discrete and identifiable class of "persons" (identified as "sectors" below). This prohibition extends to each class (or sector) individually. If a matter affects all sectors or if a particular matter affects a combination of sectors, including the ones listed below, then I understand that I do not have a financial conflict of interest.

RECUSAL LIST – INDIVIDUAL SECTORS
(b) (6)

I understand that I am also precluded from participating personally and substantially in any determination, request or recommendation that specially relates to or affects the salary or benefits of my spouse, (b) (6) Therefore, pursuant to 18 U.S.C. 5 208 and 5 C.F.R. 5 2635.502, I am recusing myself from participating in any award, promotion, or any other personnel or administrative matter, recommendation or decision that involves my spouse as a specific party.

I understand that I am responsible for not participating personally and substantially in any particular matter that will affect my financial interests. By providing this formal recusal statement to you, the immediate Office of the Office of Pesticides Program (OPP), and to the OPP management team, I am asking that other employees assist me in referring potential recusal issues to others without my participation or knowledge. If they or I have any questions, then we will consult with you as the Deputy Ethics Official or Debby Sisco as the Assistant Deputy Ethics Official, or we will contact OGC/Ethics.

In consultation with OGC/Ethics, I will revise and update my recusal statement whenever warranted by changed circumstances, including changes in my financial interests, changes in my personal or business relationships, and/or when I change positions within EPA. In the event of any changes to this screening arrangement, I will provide a copy of the revised recusal statement to the appropriate individuals and to OGC/Ethics.

cc: OPP Immediate Office
OPP Management Team
Debby Sisco, Assistant Deputy Ethics Official
Justina Fugh, Director, Ethics Law Office

From:	Lowit, Anna
To:	Messina, Edward; Keigwin, Richard; Goodis, Michael; Layne, Arnold; Dinkins, Darlene; Jewell, Shannon; Hartman, Mark; Henry, Tala; Dawson, Jeffrey; Pease, Anita
Cc:	Griffo, Shannon; Fugh, Justina
Subject:	Updated recusal
Date:	Thursday, September 2, 2021 9:52:18 AM
Attachments:	Anna Lowit recusal statement 9_2_21.pdf image003.jpg

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Ed and others

With help from OGC, I've updated my recusal. I have gotten some clarity from OGC on support for OPPT.

From Shannon: "Based on our discussion, and then my follow-up conversation with Jeff Dawson about the PFAS work, I've learned that these are really matters of general science and determined there is no distinct effect on one industry. The PFAS work involves studies for test orders, and the TSCA-related project involves work on a database of toxicity information. So for our conflicts analysis purposes, we focus on the fact that a multitude of sectors could be affected, which makes it too broad of a group to qualify as a "distinct and identifiable class." And for those reasons, we've determined that these are broader "matters" and not particular matters of general applicability."

So, it appears that I am OK to support the science discussion on-going on the PFAS test orders and the new ORD project to develop new high thru put data and computational models to support industrial chemicals.

Please let me know if you have any Qs.

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 703-308-4135
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Washington, DC 20460

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 2, 2021

MEMORANDUM

SUBJECT: Recusal Statement

FROM: Anna B. Lowit, Ph.D.
Senior Science Advisor

TO: Edward Messina, Director and Deputy Ethics Official
Office of Pesticide Programs

This memorandum formally notifies you of my continuing obligation to recuse myself from participating personally and substantially in certain matters in which I have a financial interest, or a personal or business relationship.

FINANCIAL CONFLICTS OF INTEREST

As required by 18 U.S.C. § 208(a), I will not participate personally and substantially in any particular matter in which I know that I have a financial interest directly and predictably affected by the matter, or in which I know that a person whose interests are imputed to me has a financial interest directly and predictably affected by the matter, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I understand that the interests of the following persons are imputed to me: any spouse or minor child of mine; any general partner of a partnership in which I am a limited or general partner; any organization in which I serve as officer, director, trustee, general partner or employee; and any person or organization with which I am negotiating or have an arrangement concerning prospective employment.

As an employee of the Office of Pesticides Programs (OPP), I understand that I am subject to the EPA supplemental regulation at 5 C.F.R. § 6401.102(a)(2) that prohibits me from having outside employment with or holding stock or any other financial interest in any company that manufactures or provides wholesale distribution of pesticide products registered by the EPA. I further understand that these restrictions apply to companies with subsidiaries in these areas but do not include retail distributors to the general public. In accordance with 5 C.F.R. § 6401.102(b), I have requested and received a written waiver determination from the EPA

supplemental regulation at 5 C.F.R. § 6401.102(a)(2) for my financial interests in (b) (6) [redacted], both of which are current registrants.

I am disqualified from participating personally and substantially in any particular matter that will have a direct and predictable effect upon any of the following entities as a specific party:

RECUSAL LIST – SPECIFIC PARTY MATTERS		
(b) (6) [redacted]	[redacted]	[redacted]

Because of the current level of financial ownership, I am also disqualified from participating personally and substantially in any particular matter of general applicability that is focused on the interests of any individual discrete and identifiable class of "persons" (identified as "sectors" below). This prohibition extends to each class (or sector) individually. If a matter affects all sectors or if a particular matter affects a combination of sectors, including the ones listed below, then I understand that I do not have a financial conflict of interest.

RECUSAL LIST – SECTORS	
(b) (6) [redacted]	[redacted]

RECUSAL REGARDING MY SPOUSE

I understand that I am also precluded from participating personally and substantially in any determination, request or recommendation that specifically relates to or affects the salary or benefits of my spouse, (b) (6) [redacted], who also works in OPP. Therefore, pursuant to 18 U.S.C. § 208 and 5 C.F.R. § 2635.502, I will recuse myself from participating in any award, promotion or any other personnel or administrative matter that involves my spouse as a specific party.

DIRECTIVE AND CONCLUSION

I understand that I am responsible for not participating personally and substantially in any particular matter that will affect my financial interests. By providing this formal recusal statement to you, the immediate office OPP, and the OPP management team, I am asking that other employees assist me in referring potential recusal issues to others without my participation or knowledge. If they or I have any questions, then we will consult with you as the Deputy Ethics Official, or Shannon Jewell or Carla Theriault, as the Assistant Deputy Ethics Officials, or we will contact OGC/Ethics.

In consultation with OGC/Ethics, I will review and update my recusal statement whenever warranted by changed circumstances, including changes in my financial interests, changes in my personal or business relationships, and/or when I change positions within EPA.

In the event of any changes, I will provide a copy of any revised recusal statement to the appropriate individuals and to OGC/Ethics.

cc: OPP Immediate Office
OPP Management Team
Shannon Jewell, Assistant Deputy Ethics Official
Carla Theriault, Assistant Deputy Ethics Official
Justina Fugh, Director, Ethics Office

From:	Messina, Edward
To:	Lowit, Anna; Keigwin, Richard; Goodis, Michael; Layne, Arnold; Dinkins, Darlene; Jewell, Shannon; Hartman, Mark; Henry, Tala; Dawson, Jeffrey; Pease, Anita
Cc:	Griffo, Shannon; Fugh, Justina
Subject:	RE: Updated recusal
Date:	Thursday, September 2, 2021 10:11:44 AM
Attachments:	image001.jpg

Thank you.

_____

Ed Messina, Esq.
Director, Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
p: (703) 347-0209

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, September 2, 2021 9:52 AM
To: Messina, Edward <Messina.Edward@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Jewell, Shannon <jewell.shannon@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
Cc: Griffo, Shannon <Griffo.Shannon@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Subject: Updated recusal

Ed and others

With help from OGC, I've updated my recusal. I have gotten some clarity from OGC on support for OPPT.

From Shannon: "Based on our discussion, and then my follow-up conversation with Jeff Dawson about the PFAS work, I've learned that these are really matters of general science and determined there is no distinct effect on one industry. The PFAS work involves studies for test orders, and the TSCA-related project involves work on a database of toxicity information. So for our conflicts analysis purposes, we focus on the fact that a multitude of sectors could be affected, which makes it too broad of a group to qualify as a "distinct and identifiable class." And for those reasons, we've determined that these are broader "matters" and not particular matters of general applicability."

So, it appears that I am OK to support the science discussion on-going on the PFAS test orders and the new ORD project to develop new high thru put data and computational models to support industrial chemicals.

Please let me know if you have any Qs.

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
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Mobile: +1 703-258-4209
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1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Lowit, Anna
To: Henry, Tala; Hartman, Mark; Keigwin, Richard; Barkas, Jessica; Griffo, Shannon; Fugh, Justina
Subject: Anna"s updated recusal
Date: Monday, February 14, 2022 1:58:20 PM
Attachments: Anna Lowit recusal statement OPPT detail 2-2022.pdf
image001.png

Hi everyone,

For your records, my updated recusal for the Detail.

Thanks

Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Recusal Statement

Senior Science Advisor

TO: Mark Hartman, Deputy Director for Management and Deputy Ethics Official
Office of Pollution Prevention and Toxics

This memorandum formally notifies you of my continuing obligation to recuse myself from participating personally and substantially in certain matters in which I have a financial interest, or a personal or business relationship.

FINANCIAL CONFLICTS OF INTEREST

As required by 18 U.S.C. § 208(a), I will not participate personally and substantially in any particular matter in which I know that I have a financial interest directly and predictably affected by the matter, or in which I know that a person whose interests are imputed to me has a financial interest directly and predictably affected by the matter, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2). I understand that the interests of the following persons are imputed to me: any spouse or minor child of mine; any general partner of a partnership in which I am a limited or general partner; any organization in which I serve as officer, director, trustee, general partner or employee; and any person or organization with which I am negotiating or have an arrangement concerning prospective employment.

I am disqualified from participating personally and substantially in any particular matter that will have a direct and predictable effect upon any of the following entities as a specific party:

RECUSAL LIST – SPECIFIC PARTY MATTERS		
(b) (6)	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Because of the current level of financial ownership, I am also disqualified from participating personally and substantially in any particular matter of general applicability that is focused on the interests of any individual discrete and identifiable class of "persons" (identified as "sectors" below). This prohibition extends to each class (or sector) individually. If a matter affects all sectors or if a particular matter affects a combination of sectors, including the ones listed below, then I understand that I do not have a financial conflict of interest.

RECUSAL LIST – SECTORS	
(b) (6) [redacted]	[redacted]

RECUSAL REGARDING MY SPOUSE

I understand that I am also precluded from participating personally and substantially in any determination, request or recommendation that specifically relates to or affects the salary or benefits of my spouse, (b) (6) [redacted], who works in the Office of Pesticide Programs. Therefore, pursuant to 18 U.S.C. § 208 and 5 C.F.R. § 2635.502, I will recuse myself from participating in any award, promotion or any other personnel or administrative matter that involves my spouse as a specific party.

DIRECTIVE AND CONCLUSION

I understand that I am responsible for not participating personally and substantially in any particular matter that will affect my financial interests. By providing this formal recusal statement to you, the Deputy Assistant Administrator for Management, and the immediate office OPPT, I am asking that other employees assist me in referring potential recusal issues to others without my participation or knowledge. If they or I have any questions, then we will consult with you as the Deputy Ethics Official, or Jessica Barkas as the Assistant Deputy Ethics Official, or we will contact OGC/Ethics.

In consultation with OGC/Ethics, I will review and update my recusal statement whenever warranted by changed circumstances, including changes in my financial interests, changes in my personal or business relationships, and/or when I change positions within EPA. In the event of any changes, I will provide a copy of any revised recusal statement to the appropriate individuals and to OGC/Ethics.

cc: OPPT Immediate Office
Richard Keigwin, Deputy Assistant Administrator for Management
Jessica Barkas, Assistant Deputy Ethics Official
Justina Fugh, Director, Ethics Office

From: Fugh, Justina
To: Lowit, Anna
Cc: Sisco, Debby
Subject: CORRECTED: Cautionary note about your financial interests
Date: Wednesday, November 15, 2017 5:13:00 PM
Attachments: ALowit Recusal 2016.pdf

Dear Anna --

In reviewing your annual OGE-278 (Public Financial Disclosure Report) in INTEGRITY, we noticed that you reported owning certain interests that might be affected by the performance of your official duties. These assets appear to be over the regulatory thresholds, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure to that your private interests (including your assets) do not conflict with your public duties. Be vigilant!

Why Do We Raise Concerns?

A criminal statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that affects any of your own interests or any imputed interest (e.g., spouse or dependent children). Your interests include not only ownership interests (e.g., stock, bonds, mutual funds) but also the interests of outside entities (e.g., any organization in which you are serving as an officer, director, or trustee) and prospective employers (any entity with which you are seeking future employment). So you can't participate in any particular matter that will have a direct and predictable effect on your financial interest.

The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

What is a particular matter?

A "particular matter" involves any deliberation, decision or action and that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

What is "personal and substantial" participation?

Personal participation means that you were personally involved in the matter or that you directed or controlled a subordinate's participation. Substantial participation means that your involvement in the matter was of significance, which includes decision-making, review or recommendation as to an action being taken, signing or approving a final document, and/or participating in a final decision briefing.

What is a "direct and predictable" effect on a financial interest?

The effect must be direct and predictable and not speculative (though the actual dollar amount does not need to be ascertained). There must be close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.

YOUR FINANCIAL INTEREST(S) OF CONCERN

We identified the following financial interest(s) that may be affected by the performance of your official duties and that exceed the regulatory exemption levels. This does not necessarily mean that you have a current conflict of interest, but we want to flag the asset(s) for you:

- (b) (6) [redacted]

In fact, we note that your ownership interests in both (b) (6) are over the regulatory exemption level for participating in matters of general applicability, so we expect that you are already recused from working in the same sectors as those businesses (e.g., (b) (6) etc.). We suggest that you revise and reissue your recusal statement to address (b) (6) which is now over the threshold for particular matters of general applicability. As a reference, I have attached the last signed recusal we have on file for you.

Regulatory Exemption Levels

There are different regulatory exemption levels, depending on the type of particular matter. You can still participate if you own less than the levels below:

SPECIFIC PARTY MATTER e.g., an enforcement action against ABC Widget Company	MATTER OF GENERAL APPLICABILITY e.g., working on a rulemaking that affects all widget manufacturers
≤$15,000 aggregate in ABC Widget Co. ≤$25,000 aggregate for any affected non-parties (e.g., DEF Widget Corp. which manufactures a similar product)	≤$25,000 aggregate in any one widget maker (e.g., ABC Widget Corp. or DEF Widget Corp.) ≤$50,000 aggregate in all affected parties (all widget makers)

Don't forget that you have to add together your own ownership interest and any imputed interest. You also have to aggregate how many assets you own in the same sector.

> EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.
>
> EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

What to do if you're worried about a conflict

If you are concerned that you have a conflict, contact OGC/Ethics immediately. We will go over the available options for you. Typically, potential conflict of interests are resolved in one of the following ways:

1) Don't participate. This means that you do not participate in the matter at all, including attending meetings, receiving briefings or being copied on substantive documents. We recommend that you document your recusal in writing, with a copy to OGC/Ethics.

2) Divest entirely or get below the regulatory threshold. You can either sell outright on your own or, if the sale will result in a tax liability for capital gains, then you may instead contact OGC/Ethics for a "Certificate of Divestiture" before you sell. This will enable you to defer capital gains tax, but you have to ask OGC/Ethics for assistance before you divest.

3) Ask for a waiver. Only the Agency's Designated Agency Ethics Official (DAEO) in OGC is authorized to waive the prohibition of 18 U.S.C. §208(a) where the interest is "not so substantial as to be deemed likely to affect the integrity of services which the Government may expect." OGC must consult with another federal agency before issuing a waiver, which are rarely granted.

* * * * *

If you need more information or advice, feel free to contact OGC/Ethics at ethics@epa.gov or any of us individually (Justina Fugh, Jeanne Duross, Margaret Ross, Jennie Keith or Shannon Griffo). Any of us will be happy to assist you.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Recusal and Screening Arrangement

FROM: Anna B. Lowit, Ph.D
Senior Science Advisor 6/16/2016

TO: Jack Housenger, Director and Deputy Ethics Official
Office of Pesticide Programs

This memorandum provides you with written notification of my obligation to recuse from certain matters in which I have a financial interest, or a personal or business relationship. Because of the current level of my financial ownership, I am disqualified from participating personally and substantially in any particular matter that affects the following entities as specific parties:

RECUSAL LIST – SPECIFIC PARTY MATTERS			
	(b) (6)		(b) (6)

In addition, I am disqualified from participating personally and substantially in any particular matter of general applicability that is focused on the interests of any individual discrete and identifiable class of "persons" (identified as "sectors" below). This prohibition extends to each class (or sector) individually and includes, for example, the anticipated implementation of new TSCA legislation. If a matter affects all sectors or if a particular matter affects a combination of sectors, including the ones listed below, then I understand that I do not have a financial conflict of interest.

RECUSAL LIST – INDIVIDUAL SECTORS			
	(b) (6)		(b) (6)

In order to ensure that I do not participate in matters relating to any of the entities listed above, I have taken or will take the following steps:

1. My supervisor, Jack Housenger, and Richard Keigwin will screen all EPA matters directed to my attention that involve outside entities or that require my participation, to determine if they involve any of the entities or sectors listed above.

2. If Jack Housenger or Richard Keigwin determine that a particular matter will directly involve any of the companies listed on my "specific party" recusal list, then he will refer it for action or assignment to another, without my knowledge or involvement. If he identifies a particular matter of general applicability that is focused on the interests of any of the individual sectors on my recusal list, then he will refer it for action or assignment to another, without my knowledge or involvement.

3. In the event that Richard Keigwin is unsure whether an issue is a particular matter from which I am recused, then he will consult with Jack Housenger, the Deputy Ethics Official, or Debby Sisco, the Assistant Deputy Ethics Official, who will consult with the Office of General Counsel's Ethics Office for a determination.

4. I will provide a copy of this memorandum to my supervisor, the Immediate Office of the Office of Pesticide Programs (OPP), to the OPP management team, and to Justina Fugh, Senior Counsel for Ethics.

Please note that I am also precluded from participating personally and substantially in any determination, request or recommendation that specially relates to or affects the salary or benefits of my spouse, (b) (6) Therefore, pursuant to 18 U.S.C. § 208 and 5 C.F.R. § 2635.502, I am recusing myself from participating in any award, promotion, or any other personnel or administrative matter, recommendation or decision that involves my spouse as a specific party.

In consultation with OGC/Ethics, I will revise and update my recusal statement whenever warranted by changed circumstances, including changes in my financial interests, changes in my personal or business relationships, and/or when I change positions within EPA. In the event of any changes to this screening arrangement, I will provide a copy of the revised recusal statement to the appropriate supervisor, OGC/Ethics, and any principal subordinates.

cc: Richard Keigwin, Deputy Office Director
OPP immediate office
OPP management team
Debby Sisco, Assistant Deputy Ethics Official
Justina Fugh, Senior Counsel for Ethics

Dear Anna --

In reviewing your new entrant OGE-278 (Public Financial Disclosure Report) in INTEGRITY, we noticed that you reported owning certain interests that might be affected by the performance of your official duties. These assets appear to be over the regulatory thresholds, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure to that your private interests (including your assets) do not conflict with your public duties. Be vigilant!

Why Do We Raise Concerns?

A criminal statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that affects any of your own interests or any imputed interest (e.g., spouse or dependent children). Your interests include not only ownership interests (e.g., stock, bonds, mutual funds) but also the interests of outside entities (e.g., any organization in which you are serving as an officer, director, or trustee) and prospective employers (any entity with which you are seeking future employment). So you can't participate in any particular matter that will have a direct and predictable effect on your financial interest.

The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

What is a particular matter?

A "particular matter" involves any deliberation, decision or action and that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

What is "personal and substantial" participation?

Personal participation means that you were personally involved in the matter or that you directed or controlled a subordinate's participation. Substantial participation means that your involvement in the matter was of significance, which includes decision-making, review or recommendation as to an action being taken, signing or approving a final document, and/or participating in a final decision briefing.

What is a "direct and predictable" effect on a financial interest?

The effect must be direct and predictable and not speculative (though the actual dollar amount does not need to be ascertained). There must be close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.

YOUR FINANCIAL INTEREST(S) OF CONCERN

We identified the following financial interest(s) that may be affected by the performance of your official duties and that exceed the regulatory exemption levels. This does not necessarily mean that you have a current conflict of interest, but we want to flag the asset(s) for you:

- (b) (6) [redacted]

In fact, we note that your ownership interest in (b) (6) is over the regulatory exemption level for participating in matters of general applicability, so we would expect that you are already recused from working in TSCA.

Regulatory Exemption Levels

There are different regulatory exemption levels, depending on the type of particular matter. You can still participate if you own less than the levels below:

SPECIFIC PARTY MATTER e.g., an enforcement action against ABC Widget Company	MATTER OF GENERAL APPLICABILITY e.g., working on a rulemaking that affects all widget manufacturers
≤$15,000 aggregate in ABC Widget Co.	≤$25,000 aggregate in any one widget maker (e.g., ABC Widget Corp. or DEF Widget Corp.)
≤$25,000 aggregate for any affected non-parties (e.g., DEF Widget Corp. which manufactures a similar product)	≤$50,000 aggregate in all affected parties (all widget makers)

Don't forget that you have to add together your own ownership interest and any imputed interest. You also have to aggregate how many assets you own in the same sector.

> EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.
>
> EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

What to do if you're worried about a conflict

If you are concerned that you have a conflict, contact OGC/Ethics immediately. We will go over the available options for you. Typically, potential conflict of interests are resolved in one of the following ways:

1) Don't participate. This means that you do not participate in the matter at all, including attending meetings, receiving briefings or being copied on substantive documents. We recommend that you document your recusal in writing, with a copy to OGC/Ethics.

2) Divest entirely or get below the regulatory threshold. You can either sell outright on your own or, if the sale will result in a tax liability for capital gains, then you may instead contact OGC/Ethics for a "Certificate of Divestiture" before you sell. This will enable you to defer capital gains tax, but you have to ask OGC/Ethics for assistance before you divest.

3) Ask for a waiver. Only the Agency's Designated Agency Ethics Official (DAEO) in OGC is authorized to waive the prohibition of 18 U.S.C. §208(a) where the interest is "not so substantial as to be deemed likely to affect the integrity of services which the Government may expect." OGC must consult with another federal agency before issuing a waiver, which are rarely granted.

* * * * *

If you need more information or advice, feel free to contact OGC/Ethics at ethics@epa.gov or any of us individually (Daniel Fort, Justina Fugh, Jeanne Duross, Jennie Keith). Any of us or your regional ethics counselor will be happy to assist you.

Message

From: Ross, Margaret [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=38CAF91847DD4F95810C1F96D918871C-ROSS, MARGARET]
Sent: 2/5/2019 2:53:12 PM
To: Margaret Ross (Ross.Margaret@epa.gov) [Ross.Margaret@epa.gov]
BCC: Abboud, Michael [abboud.michael@epa.gov]; Allen, Reginald [Allen.Reginald@epa.gov]; Allnutt, David [Allnutt.David@epa.gov]; Amon, Dan [Amon.Dan@epa.gov]; Anastas, Nicholas [Anastas.Nicholas@epa.gov]; Ankley, Gerald [Ankley.Gerald@epa.gov]; Ashbee, Blake [ashbee.blake@epa.gov]; Avila, Aaron [avila.aaron@epa.gov]; Badalamente, Mark [Badalamente.Mark@epa.gov]; Bagley, Mark [Bagley.Mark@epa.gov]; Bahadori, Tina [Bahadori.Tina@epa.gov]; Banister, Beverly [Banister.Beverly@epa.gov]; Baptist, Erik [baptist.erik@epa.gov]; Barnet, Henry [Barnet.Henry@epa.gov]; Barone, Stan [Barone.Stan@epa.gov]; Barr, Pamela [Barr.Pamela@epa.gov]; Battaglia, Amy [Battaglia.Amy@epa.gov]; Battin, Andrew [Battin.Andrew@epa.gov]; Beach, Christopher [beach.christopher@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Behl, Betsy [Behl.Betsy@epa.gov]; Benevento, Douglas [benevento.douglas@epa.gov]; Benforado, Jay [Benforado.Jay@epa.gov]; Benjamin-Sirmons, Denise [Benjamin-Sirmons.Denise@epa.gov]; Bennett, Tate [Bennett.Tate@epa.gov]; 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Subject: Public Financial Disclosure Reports due May 15, 2019

Greetings Public Filers,

Last week, you received an annual financial disclosure report assignment from INTEGRITY.gov. This report covers calendar year 2018. The deadline for annual reports is 5/15/19. If you believe that you have received this assignment in error, or if you need assistance with your report, please contact Margaret Ross at Ross.margaret@epa.gov.

Thanks,
Margaret

Margaret Ross | Ethics Officer | Office of General Counsel | US EPA | William Jefferson Clinton Federal Building Room 4310A North | Washington, DC 20460 (for ground deliveries: 20004) | phone 202-564-3221 |work cell 202-527-0432

From: Fugh, Justina
To: Lowit, Anna; Griffo, Shannon
Subject: RE: not sure if this is what you are looking for?
Date: Tuesday, August 24, 2021 3:00:00 PM

Great! It shows that you asked so the approval is probably someplace in the office in hard copy. Thanks!

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, August 24, 2021 2:48 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Subject: not sure if this is what you are looking for?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

To: Jack Housenger, Deputy Ethics Official
Office of Pesticide Programs

Debby Sisco, Assistant Deputy Ethics Official

From: Anna B. Lowit
Immediate Office
Health Effects Division, MC7509P

Subject: Request for Waiver of 5 CFR 6401 Prohibition on Certain Financial Interests

I am requesting a waiver from having to divest myself of stock that my husband holds in (b) (6) in accordance with 5 CFR 6401.102(b). I have reviewed Subpart A of 5 CFR 2635 and believe that maintaining the holdings (b) (6) is consistent with these regulations.

The holdings belong to my husband, (b) (6), and have approximate values of (b) (6)

I am a senior scientist in the Immediate Office of the Health Effects Division. My duties include review and analysis of toxicology data and conduct of human health risk assessment. I also support the Office by training new staff and leading cross-cutting new science initiatives.

I have recused (disqualified) myself from participation in all activities that would have direct and predictable effect on the financial interests of (b) (6)

From:	Fugh, Justina
To:	Lowit, Anna
Cc:	Sisco, Debby
Subject:	RE: CORRECTED: Cautionary note about your financial interests
Date:	Sunday, February 11, 2018 11:39:00 PM

Did you issue a renewed recusal and, if so, can you please send the signed and dated copy to me for my files? I sent you a cautionary note because we noticed (b) (6) on your report, so asked you to issue a recusal statement. That's what I'm looking for now.

Justina

Justina Fugh | Senior Counsel for Ethics | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Anna
Sent: Wednesday, November 22, 2017 12:57 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>
Cc: Sisco, Debby <Sisco.Debby@epa.gov>
Subject: RE: CORRECTED: Cautionary note about your financial interests

Hey Justina

Looking at this more closely, you said this in your email to me:

"We suggest that you revise and reissue your recusal statement to address (b) (6) which is now over the threshold for particular matters of general applicability. "

However, (b) (6) is already on the list in the attached PDF. What are you asking me to do?

Anna

Anna B. Lowit

Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Fugh, Justina
Sent: Wednesday, November 15, 2017 5:13 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Sisco, Debby <Sisco.Debby@epa.gov>
Subject: CORRECTED: Cautionary note about your financial interests

Dear Anna --

In reviewing your annual OGE-278 (Public Financial Disclosure Report) in INTEGRITY, we noticed that you reported owning certain interests that might be affected by the performance of your official duties. These assets appear to be over the regulatory thresholds, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure to that your private interests (including your assets) do not conflict with your public duties. Be vigilant!

Why Do We Raise Concerns?

A criminal statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that affects any of your own interests or any imputed interest (e.g., spouse or dependent children). Your interests include not only ownership interests (e.g., stock, bonds, mutual funds) but also the interests of outside entities (e.g., any organization in which you are serving as an officer, director, or trustee) and prospective employers (any entity with which you are seeking future employment). So you can't participate in any particular matter that will have a direct and predictable effect on your financial interest.

The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

What is a particular matter?

A "particular matter" involves any deliberation, decision or action and that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

What is "personal and substantial" participation?

Personal participation means that you were personally involved in the matter or that you directed or controlled a subordinate's participation. Substantial participation means that your involvement in the matter was of significance, which includes decision-making, review or recommendation as to an action being taken, signing or approving a final document, and/or participating in a final decision briefing.

What is a "direct and predictable" effect on a financial interest?

The effect must be direct and predictable and not speculative (though the actual dollar amount does not need to be ascertained). There must be close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.

YOUR FINANCIAL INTEREST(S) OF CONCERN

We identified the following financial interest(s) that may be affected by the performance of your official duties and that exceed the regulatory exemption levels. This does not necessarily mean that you have a current conflict of interest, but we want to flag the asset(s) for you:

- (b) (6) [redacted]

In fact, we note that your ownership interests in both (b) (6) [redacted] are over the regulatory exemption level for participating in matters of general applicability, so we expect that you are already recused from working in the same sectors as those businesses (e.g., (b) (6) [redacted] etc.). We suggest that you revise and reissue your recusal statement to address (b) (6) [redacted] which is now over the threshold for particular matters of general applicability. As a reference, I have attached the last signed recusal we have on file for you.

Regulatory Exemption Levels

There are different regulatory exemption levels, depending on the type of particular matter. You can still participate if you own less than the levels below:

SPECIFIC PARTY MATTER e.g., an enforcement action against ABC Widget Company	MATTER OF GENERAL APPLICABILITY e.g., working on a rulemaking that affects all widget manufacturers
≤$15,000 aggregate in ABC Widget Co. ≤$25,000 aggregate for any affected non-parties (e.g., DEF Widget Corp. which manufactures a	≤$25,000 aggregate in any one widget maker (e.g., ABC Widget Corp. or DEF Widget Corp.) ≤$50,000 aggregate in all affected parties (all

similar product)	widget makers)

Don't forget that you have to add together your own ownership interest and any imputed interest. You also have to aggregate how many assets you own in the same sector.

> EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.
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> EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

What to do if you're worried about a conflict

If you are concerned that you have a conflict, contact OGC/Ethics immediately. We will go over the available options for you. Typically, potential conflict of interests are resolved in one of the following ways:

1) Don't participate. This means that you do not participate in the matter at all, including attending meetings, receiving briefings or being copied on substantive documents. We recommend that you document your recusal in writing, with a copy to OGC/Ethics.

2) Divest entirely or get below the regulatory threshold. You can either sell outright on your own or, if the sale will result in a tax liability for capital gains, then you may instead contact OGC/Ethics for a "Certificate of Divestiture" before you sell. This will enable you to defer capital gains tax, but you have to ask OGC/Ethics for assistance before you divest.

3) Ask for a waiver. Only the Agency's Designated Agency Ethics Official (DAEO) in OGC is authorized to waive the prohibition of 18 U.S.C. §208(a) where the interest is "not so substantial as to be deemed likely to affect the integrity of services which the Government may expect." OGC must consult with another federal agency before issuing a waiver, which are rarely granted.

* * * * *

If you need more information or advice, feel free to contact OGC/Ethics at ethics@epa.gov or any of us individually (Justina Fugh, Jeanne Duross, Margaret Ross, Jennie Keith or Shannon Griffo). Any of us will be happy to assist you.

From: Fugh, Justina
To: Lowit, Anna
Cc: Sisco, Debby
Subject: CORRECTED: Cautionary note about your financial interests
Date: Wednesday, November 15, 2017 5:13:00 PM
Attachments: ALowit Recusal 2016.pdf

Dear Anna --

In reviewing your annual OGE-278 (Public Financial Disclosure Report) in INTEGRITY, we noticed that you reported owning certain interests that might be affected by the performance of your official duties. These assets appear to be over the regulatory thresholds, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure to that your private interests (including your assets) do not conflict with your public duties. Be vigilant!

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The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

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YOUR FINANCIAL INTEREST(S) OF CONCERN

We identified the following financial interest(s) that may be affected by the performance of your official duties and that exceed the regulatory exemption levels. This does not necessarily mean that you have a current conflict of interest, but we want to flag the asset(s) for you:

- (b) (6) [redacted]

In fact, we note that your ownership interests in both [redacted] are over the regulatory exemption level for participating in matters of general applicability, so we expect that you are already recused from working in the same sectors as those businesses (e.g., [redacted] etc.). We suggest that you revise and reissue your recusal statement to address [redacted] which is now over the threshold for particular matters of general applicability. As a reference, I have attached the last signed recusal we have on file for you.

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≤$15,000 aggregate in ABC Widget Co. **≤$25,000 aggregate for any affected non-parties (e.g., DEF Widget Corp. which manufactures a similar product)**	**≤$25,000 aggregate in any one widget maker (e.g., ABC Widget Corp. or DEF Widget Corp.)** **≤$50,000 aggregate in all affected parties (all widget makers)**

Don't forget that you have to add together your own ownership interest and any imputed interest. You also have to aggregate how many assets you own in the same sector.

> EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.
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> EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

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* * * * *

If you need more information or advice, feel free to contact OGC/Ethics at ethics@epa.gov or any of us individually (Justina Fugh, Jeanne Duross, Margaret Ross, Jennie Keith or Shannon Griffo). Any of us will be happy to assist you.

From:	Griffo, Shannon
To:	Lowit, Anna
Subject:	RE: Draft recusal statement for OPPT detail
Date:	Friday, February 11, 2022 1:38:00 PM
Attachments:	Anna Lowit draft recusal statement OPPT detail.docx image001.png

Works for me! I just made some minor edits to that paragraph.
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Friday, February 11, 2022 12:16 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: RE: Draft recusal statement for OPPT detail
How about this for cc's? I kept Mark for now since the OD is supposed to be my supervisor.

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Thursday, February 10, 2022 3:54 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: Draft recusal statement for OPPT detail
Hi Anna,
I modified your OPP recusal statement to reflect your upcoming detail in OPPT. You'll see I have a few comments in the attached, mainly about who to address it to and who gets a copy. I also deleted the paragraph about the OPP waiver from the supplemental ethics regulation.
I double checked your transaction reports to see if we needed to add or remove any companies or sectors. I noticed you had (b) (6), (b) (3) (A) [redacted] If the value of any of those are now (b) (6) [redacted], please let me know so we can add it to your chart.
Let me know if you have any other questions!
Thanks,
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna
To: Griffo, Shannon
Subject: Re: error on my report
Date: Monday, May 16, 2022 6:14:27 PM
Attachments: image001.png
image001.png

Thanks, I resubmitted

Sent from my iPhone

> On May 16, 2022, at 7:18 AM, Griffo, Shannon <Griffo.Shannon@epa.gov> wrote:
>
> I sent it back to you in INTEGRITY. Just make sure you hit "submit" when you're done so it'll come back to me for review. Thanks!
> Shannon Griffo
> Office of General Counsel, Ethics Office
> U.S. Environmental Protection Agency
> (202) 564-7061
>
> ---
>
> **From:** Lowit, Anna <Lowit.Anna@epa.gov>
> **Sent:** Saturday, May 14, 2022 11:46 AM
> **To:** Griffo, Shannon <Griffo.Shannon@epa.gov>
> **Subject:** error on my report
> Shannon
> I just realized I made a mistake on my annual report for Integrity. Can you 'unsubmit' it for me so I can fix it?
> Sorry
> Anna

Anna B. Lowit
Senior Science Advisor, Acting
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pollution Prevention and Toxics
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Lowit, Anna
To: Griffo, Shannon
Subject: RE: Financial Disclosure Report - Cautionary Guidance
Date: Tuesday, August 10, 2021 4:01:19 PM

Hi Shannon
Sorry for the delay, as requested here are the rounded amounts for the stocks you listed.
(b) (6) [redacted]
I'll be on (b) (6) [redacted]. Because of some requests from the OCSPP AA for OPPT support, I'm hoping to get my updated recusal completed the week that I'm back. I'd also like to have a conversation about specific projects to make sure I understand my limitations in what support I can/not provide to OPPT.
Thanks
Anna

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Monday, July 19, 2021 3:43 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: Financial Disclosure Report - Cautionary Guidance
Hi Anna,
Apologies for not being clearer – yes, I certified your report around the same time I sent out this cautionary guidance. I checked our electronic files, and I see a recusal statement dated April 2019. Was there a more recent version? I'm not sure if you worked with OPPT ethics officials or OGC/Ethics to draft that one, but I'm happy to assist with creating an updated one. It'd be helpful to have more specifics about the amounts you own in the assets I flagged below. Then I can put together a chart, aggregate sectors as needed, and draft an updated version for you.
I was just reviewing your most recent periodic transaction report, and I'll get that certified today as well.
Thanks!
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>

Sent: Monday, July 19, 2021 3:09 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: RE: Financial Disclosure Report - Cautionary Guidance
Hi Shannon
I assume I need to update my recusal but I had hoped to do that after my annual form was approved. I have not gotten the notification that this has occurred? Do you know the status of my annual reporting?
I expect be asked soon by our AA to provide more support for OPPT than I've done in the past. So, I want to have an updated recusal---and a strong understanding of my limitations in OPPT support.
Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Wednesday, June 09, 2021 4:30 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: Financial Disclosure Report - Cautionary Guidance
Hi Anna,
In reviewing your OGE-278 (Financial Disclosure Report), we noticed that you reported owning certain interests that may possibly be affected by the performance of your official duties. This will sound familiar to the advice you've received in the past, but these assets appear to be over the regulatory thresholds, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure that your private interests (including your assets) do not conflict with your public duties. Be vigilant!
YOUR FINANCIAL INTERESTS OF CONCERN
We identified the following financial interests that may be affected by the performance of your official duties and that exceed the regulatory exemption levels. This does not necessarily mean that you have a current conflict of interest, but we want to flag the following for you (* denotes the value range was (b) (6)):

- (b) (6)

NOTE: Remember that if your ownership level is over $15,000, then you must recuse from specific party matters involving that company. In addition, if your ownership is above $25,000 in a single company or $50,000 across all companies in the same sector/industry, then you must also recuse from matters of general applicability that affect the sector in which the company operates (e.g. (b) (6)).
You also have holdings in other companies that, when aggregated, could put you over the regulatory thresholds. Due to the way the OGE Form 278 gathers information, the categories of earning values

are so broad that we cannot determine if you own, for example, $5,000 worth of stock, or over $75,000. Please review your holdings to make sure you are able to fulfill your ethics obligations. I believe you previously issued a recusal statement, but I don't have the most current copy. So I wanted to flag that the values of some assets increased since your last annual report (e.g., (b) (6)), so please ensure that the correct entities and sectors are reflected in your recusal statement.

Regulatory Exemption Levels

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SPECIFIC PARTY MATTER e.g., an enforcement action against ABC Widget Company	**MATTER OF GENERAL APPLICABILITY** e.g., working on a rulemaking that affects all widget manufacturers
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* * * * *

If you need more information or advice, feel free to contact me or OGC/Ethics at ethics@epa.gov . We will be happy to assist you.

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Office of General Counsel, Ethics
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Lowit, Anna
To: Griffo, Shannon
Subject: RE: Financial Disclosure Report - Cautionary Guidance
Date: Monday, July 19, 2021 4:38:57 PM

Thanks so much. I'll need to get the values from my husband (his stocks). Give me a couple days.
Anna

Anna B. Lowit

Senior Science Advisor
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US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

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To: Lowit, Anna <Lowit.Anna@epa.gov>
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***Don't forget that you have to add together your own ownership interest and any imputed interest. AND you also have to aggregate how many assets you own in the same sector.

EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.

EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

Why Do We Raise Concerns?

A criminal statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that affects any of your own interests or any imputed interest (e.g., spouse or dependent children). Your interests include not only ownership interests (e.g., stock, bonds, mutual funds) but also the interests of outside entities (e.g., any organization in which you are serving as an officer, director, or trustee) and prospective employers (any entity with which you are seeking future employment). So you can't participate in any particular matter that will have a direct and predictable effect on your financial interest.

The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

What is a particular matter?

A "particular matter" involves any deliberation, decision or action and that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

What is "personal and substantial" participation?

Personal participation means that you were personally involved in the matter or that you directed or controlled a subordinate's participation. Substantial participation means that your involvement in the matter was of significance, which includes decision-making, review or recommendation as to an action being taken, signing or approving a final document, and/or participating in a final decision briefing.

What is a "direct and predictable" effect on a financial interest?

The effect must be direct and predictable and not speculative (though the actual dollar amount does not need to be ascertained). There must be close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.

What to do if you're worried about a conflict

If you are concerned that you have a conflict, contact OGC/Ethics immediately. We will go over the available options for you. Typically, potential conflict of interests are resolved in one of the following ways:

1) Don't participate. This means that you do not participate in the matter at all, including attending meetings, receiving briefings or being copied on substantive documents. We recommend that you document your recusal in writing, with a copy to OGC/Ethics.

2) Divest entirely or get below the regulatory threshold. You can either sell outright on your own or, if the sale will result in a tax liability for capital gains, then you may instead contact OGC/Ethics for a "Certificate of Divestiture" before you sell. This will enable you to defer capital gains tax, but you have to ask OGC/Ethics for assistance before you divest.

3) Ask for a waiver. Only the Agency's Designated Agency Ethics Official (DAEO) in OGC is authorized to waive the prohibition of 18 U.S.C. §208(a) where the interest is "not so substantial as to be deemed likely to affect the integrity of services which the Government may expect." OGC must consult with another federal agency before issuing a waiver, which are rarely granted.

* * * * *

If you need more information or advice, feel free to contact me or OGC/Ethics at ethics@epa.gov . We will be happy to assist you.

Shannon Griffo
Office of General Counsel, Ethics
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Griffo, Shannon
To: Lowit, Anna
Subject: RE: Follow-up from OGC/Ethics on recusals
Date: Thursday, October 14, 2021 5:59:00 PM

You are quite welcome. Thanks for reaching out and being so mindful about your ethics obligations!
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, October 14, 2021 5:24 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: Re: Follow-up from OGC/Ethics on recusals

Thanks so much. This is the clearest explanation on this stuff I've ever seen!!
Anna

Sent from my iPhone

> On Oct 14, 2021, at 5:14 PM, Griffo, Shannon <Griffo.Shannon@epa.gov> wrote:
>
> Hi Anna,
> I spent some time going through the materials you sent me (which were very helpful!), and I followed up with Justina for her thoughts. So going back to the financial conflict of interest statute, 18 U.S.C. §208(a) – you cannot participate in any "particular matter" that has a direct and predicatable effect on your financial interests. And you'll recall from our other discussions that a "particular matter" involves any deliberation, decision or action that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.
> For this one, we're going to focus on the "direct and predictable effect on your financial interests." Justina used a great food analogy and said we should separate out the ingredients from the final product. She compared quats to the flour in your pantry. It's the ingredient that goes into numerous different things to create the end food/product. And there are *many end uses* of these ingredients as evidenced by that useful summary and documents you sent yesterday. Various products from a multitude of sectors contain a quat as an active ingredient (a.i.). Then we look at your role as Senior Science Advisor which is to concentrate on the ingredients (quats compounds or citric acid) and provide advice on general science matters/studies related to these. However, someone else ultimately decides how to use those ingredients to get to the product. You are not making any final decisions on what to make – you're just helping with the evaluation or review of reports or studies, or how to group quats etc. And

finally we look at (b) (6) role in the process – (b) (6) does the action to get to the product. (b) (6) products have a combination of a.i.s. and as you highlighted, (b) (6) is not the technical on any of these specific a.i.s. They have mixed/put together the formulations with these various ingredients to get to their final products. And it's too speculative for us to know how (b) (6) will ultimately use such compounds/ingredients in their final products.

So for purposes of the financial COI statute, a particular matter will have a predictable effect if there is a real, as opposed to a speculative possibility that the matter will affect the financial interests. We've concluded that your role in the process and your work on these general science matters related to quats and citric acid would not have a "direct and predictable effect" on the financial interests of (b) (6) because any effect on your financial interests would be indirect and too speculative. Thus, you can participate personally and substantially on these general science matters, such as the review of studies or EPA reports related to quats or citric acid.

If you have any other questions, just let me know. Happy to set up a call to discuss further.

Thanks!

Shannon

From: Griffo, Shannon
To: Lowit, Anna
Subject: RE: Follow-up from OGC/Ethics on your public financial disclosure report
Date: Thursday, May 26, 2022 2:00:00 PM
Attachments: image001.png

Yep. Makes sense to me. Just keep me posted!
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, May 26, 2022 1:45 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: RE: Follow-up from OGC/Ethics on your public financial disclosure report
Thanks Shannon. In the event that I'm asked to transition from 'detail' to 'permanent' in the next couple months (still unknown but a strong possibility), I'll want to update my recusal anyway. So, I think it makes sense to hold off for right now. does this make sense?

Anna B. Lowit
Senior Science Advisor, Acting
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pollution Prevention and Toxics
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Thursday, May 26, 2022 1:36 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: Follow-up from OGC/Ethics on your public financial disclosure report
Hi Anna,
I'm about to hit certify on your Annual Report, but wanted to touch base on your recusals. I noticed the value increased on a few assets such that you will have a specific party recusal with the following entities – (b) (6) [redacted]. You're also now going to have a sector recusal with "(b) (6) [redacted]" However, I don't see a need to add these to your recusal statement (see attached) because they're unlikely to be a conflict given your official EPA duties. All your other recusals and my previous advice (also attached) remain the same.
Hope your detail is going well and don't hesitate to reach out if you have any questions!
Thanks,
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Griffo, Shannon
To: Lowit, Anna
Subject: RE: Follow-up from OGC/Ethics on your Upcoming Detail
Date: Monday, February 7, 2022 9:43:00 AM
Attachments: image001.png

I'll get you an updated recusal this week. Thanks!
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Friday, February 4, 2022 12:01 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: RE: Follow-up from OGC/Ethics on your Upcoming Detail
Thanks so much. This is REALLY clear. I guess we should go ahead and start updating my recusal.
Have a great weekend
Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Thursday, February 3, 2022 3:21 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: Follow-up from OGC/Ethics on your Upcoming Detail
Hi Anna,
Apologies it took me a bit to get back to you. But as promised, I'm following up with a summary of your ethics restrictions, as well as the potential OPPT projects we previously discussed.

Summary of your Ethics Restrictions:

- The financial conflict of interest statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that has a direct and predicatable effect on your financial interests. A "particular matter" involves any deliberation, decision or action that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons. We've identified those specific companies and sectors in your recusal statement.
    - Speaking of recusal statement - I checked with Justina, and she said we should update your recusal statement once your detail begins so that it is addressed to OPPT. Then it can be shared among the appropriate individuals (e.g., those responsible for assigning you work).

- You are allowed to work on broader "matters" which include general matters of science that have no distinct effect on one industry. When a multitude of sectors could be affected by something you are working on, then it's too broad a group to qualify as a "distinct and identifiable class."
- Also, the particular matter must have a direct and predictable effect on your financial interests. The effect must be real, as opposed to a speculative possibility, and there must be a close causal link between any decision or action to be taken in the matter and any expected effect on your financial interest. This was the analysis we did on the "ingredients" (quats compounds; citric acid) and the various end uses of those ingredients (final products). We previously concluded that your work on the general science matters/studies related to those active ingredients would not have a "direct and predictable effect" on your financial interests. See my 10/14/21 email.

OPPT Detail – Potential Projects

Forgive me for mischaracterizing any of these projects. I didn't take many notes during our last call so I'm trying to remember what we discussed. Please let me know what I'm forgetting or if something is incorrect!

1. Lung Tox effects/study: During our call we discussed how this project was big picture/policy/related to general matters of science, and would be okay to work on.
2. PFAS database (with ORD): We previously determined that this was a broader "matter." See my 8/31/21 email.
3. Serving on a Committee: This would be fine so long as you are mindful of your specific party recusals (entity names) and sector recusals. As cases come before you for decision, we agreed to touch base as needed to determine any recusal issues.
4. SOPs related to PMNs: You may look at old cases because we determined that these cases were "closed" and your review of them will not change any past decision. And any subsequent information produced from your review would be applied to big picture/policy/SOPs/general matters of science (which would affect a multitude of sectors). However, you understand you may not work on any open/new/incoming PMNs (specific party matters) submitted by entities on your recusal list.
5. TSCA risk evaluations - 20 chemical substances designated as high priority substances for risk evaluations; cumulative risk assessments as well

   I went through the various materials you sent me - which were very helpful to understand the purpose of risk evaluations, see the use reports, and determine how many manufacturers there were of the chemicals. I also found this site to be helpful: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca because I could go to the individual chemicals and get more background and conditions of use info.

   For this one, I confirmed my analysis with Justina. Based on those materials, we'd consider these risk evaluations to be "matters" which you may work on. These chemicals are used in multiple sectors, and there are also multiple manufacturers. We'd be concerned if (b) (6) was the *only manufacturer* of one of those chemicals, because then it's more likely that there would be a direct and predictable effect on your financial interests. But for the three chemicals where (b) (6) was listed, there were other manufacturers identified.

I hope that covers everything we discussed! But please let me know if you have any other questions or if we need to discuss any of this in more detail.

Thanks!
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Griffo, Shannon
To: Lowit, Anna
Cc: Fugh, Justina
Subject: Follow-up from OGC/Ethics
Date: Tuesday, August 31, 2021 1:31:00 PM
Attachments: Anna Lowit draft recusal statement 8_30_21.docx

Hi Anna,

Thanks again for speaking with us last week about your ethics obligations. As promised, I wanted to follow-up on the two questions/projects you raised – one dealing with PFAS work and the other in the TSCA space. Ultimately, we decided that you may participate personally and substantially in both of these projects, and here's why -

As you know, the financial conflict of interest statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that has a direct and predicatable effect on your financial interests. A "particular matter" involves any deliberation, decision or action that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

Based on our discussion, and then my follow-up conversation with Jeff Dawson about the PFAS work, I've learned that these are really matters of general science and determined there is no distinct effect on one industry. The PFAS work involves studies for test orders, and the TSCA-related project involves work on a database of toxicity information. So for our conflicts analysis purposes, we focus on the fact that a multitude of sectors could be affected, which makes it too broad of a group to qualify as a "distinct and identifiable class." And for those reasons, we've determined that these are broader "matters" and not particular matters of general applicability.

I've also drafted an updated recusal statement which addresses your conflicts and waiver from EPA's supplemental regulation. Please see attached and let me know if you have any comments or questions. If you need assistance inserting a digital signature, just let me know.

Thanks!

Shannon

Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Lowit, Anna
To: Griffo, Shannon; Fugh, Justina
Subject: RE: going on detail
Date: Thursday, January 13, 2022 2:33:29 PM
Attachments: image001.jpg
image002.jpg

Thanks.

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Thursday, January 13, 2022 12:29 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Subject: RE: going on detail

Hi Anna,

Thanks for sending the scheduler. We will chat more next week about your detail!

Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Wednesday, January 12, 2022 11:03 AM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Subject: going on detail

Shannon and Justina

I need your help……I'm going on a 6-month detail to the OPPT IO to stand in as their SL Science Advisor while OPPT re-advertises the position. Can we set up a call? I'd like to get on paper/email what my limitations are with OPPT. I don't have a start date yet but will likely be in later Jan/early Feb.

Thanks

Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

F om _owit Anna
To __ff__h_____
Subject RE Integ ity gov iling Reminde Assignment
Da e Monday Sep embe 20 2021 9 53 14 AM

Thanks.

Anna B. Lowit

Senior Science Ad sor
US En ironmental Protection Agency
Office of Chemical Safety and Po lution Pre en ion
Office of Pest cide Programs

Phone 1 703-308- 135
Mobile 1 703-258- 209
Email lowi .anna@epa.go

MC7501PY
1200 Pennsyl an a A enue N.W.
Washington DC 20 60

----O iginal Message ----
From Griffo Shannon <G iffo.Shannon@epa.go >
Sent Monday Sep ember 20 2021 9 32 AM
To Lowit Anna <Lowi .Anna@epa.go >
Subject RE Integri y go F ling Rem nder Assignment

Deleted!

Shannon Gr ffo
Office of Gene al Counsel Ethics Off ce U.S. En ironmental Pro ection Agency
202) 56 -7061

----O iginal Message ----
From Lowit Anna <Low t.Anna@epa.go >
Sent Fr day September 17 2021 6 25 PM
To Griffo Shannon <Gr ffo.Shannon@epa go >
Subject Re In egr ty.go Fil ng Reminder Assignment

Thanks so much!

Sent from my iPhone

> On Sep 17 2021 at 5 0 PM Gri fo Shannon <Griffo Shannon@epa.go > wrote
>
> I should be able to go in on my end Monday morning and delete t for you. I'll let you know when it's done.
>
> Ha e a g eat weekend!
>
> Sent f om my iPhone
>
>> On Sep 17 2021 at 59 PM Lowit Anna <Lowi .Anna@epa.go > wro e
>>
>> Shannon
>>
>> I need help w th something in In egr ty. I had sta ted (but didn't finish or subm t) a 278 eport last month- -that I didn't need. So now there s an unfinished repo t n my profile. How do I delete it? I'm gett ng reminde s that it's due on 10/1 but I don't ha e anything to eport.
>>
>>
>> Anna B. Low t
>>
>> Sen or Sc ence Ad isor
>> US En i onmental Protect on Agency
>> Office of Chem cal Safe y and Pollu ion P e ention O fice of
>> Pe ticide Programs
>>
>> Phone 1 703-308- 135
>> Mob le 1 703-258- 209
>> Ema l lowit anna@epa.go
>>
>> MC7501PY
>> 1200 Pennsyl ania A enue N.W.
>> Wash ngton DC 20 60
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>>
>>
>> --- -Orig nal Message--- -
>> From Integr ty.go <notif ca ions@ n egr ty.go >
>> Sent Wednesday Sep ember 15 2021 7 2 PM
>> To Low t Anna <Lowit.Anna@epa go >
>> Subject Integri y go F ling Rem nder Assignment
>>
>> REMINDER Your 2021 Periodic Transaction report s due on 10/01/2021. Failure to file t mely sub ects you to a $200 late fil ng fee. Remember here's no penalty for fil ng early (also fil ng your report will stop hese annoy ng reminders).
>>
>> You may access the report by logging n o Integrity at https /gcc02.safelinks pro ection.ou look com ?
url=ht ps%3A%2F%2Fintegrity go %2F&amp data=0 %7C01%7CGriffo.Shannon% 0epa.go %7C3ab79bf9b3f2 f7319e808d97c3dfca0%7C88b378b367 8 867acf976aacbeca6a7%7C0%7C0%7C637677 279 0 550 7%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWw LCJXVCI6Mn0%3D%7C1000&amp sdata=Uwbw R6%2BIMDCT75RWwPxF5Dorr AP5fR a3AUG 9bVE%3D&amp eser ed=0.
f you ha e any que tions about your fil ng send a no e to e h cs@epa.go .
>>
>> If you need an extens on send an email to ethics@epa go . You need to gi e a eason (e g. wo kload tra el need o ga her mater als) and say whether you need 5 or 90 addi ional days.
>>
>> For add tional guidance about f ll ng out the OGE-278 annual and
>> OGE-278-T periodic financial disclosure form see
>> https /gcc02.safelinks pro ection.ou look com ?url=ht ps%3A%2F%2Fwww
>> 2.oge go %2FWeb%2F278eGuide.nsf&amp data=0 %7C01%7CGriffo Shannon% 0e
>> pa.go %7C2726bb71 6a1 c625add08d97a29f3d2%7C88b378b367 8 867acf976aac
>> beca6a7%7C0%7C0%7C6376751 2870 19368%7CUnknown%7CTWFpbGZsb3d8eyJWIjoi
>> MC wL AwMDA LCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&amp
>> sdata=uTWiN5AwX3180fus55Ohak6AQCpLk8puwuG%2BG9LZPCI%3D&amp reser ed=
>> 0

From: Ross, Margaret
To: Clarke, Victoria
Cc: Fugh, Justina
Subject: FW: Please respond ASAP
Date: Tuesday, June 11, 2019 3:35:09 PM
Attachments: cautionary note for 2018 filing.docx
draft of recusal following 2018 review of 278.docx

It appears that Anna Lowit still has not come to closure on her 2018 report. The report is with her, and there are pending questions, and she hasn't been into the report since Justina returned it to her on 1/10/19.
Can I request a Victoria follow up?

Margaret Ross | Ethics Officer | Office of General Counsel | US EPA | William Jefferson Clinton Federal Building Room 4310A North | Wash ngton, DC 20460 (for ground deliveries: 20004) | phone 202-564-3221 |work cell 202-527-0432

From: Fugh, Justina
Sent: Wednesday, April 3, 2019 5:18 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: Please respond ASAP

Anna,

PLEASE come to closure on your CY 2017 report! Then you can start your CY 2018 report (that is due May 15, 2019) with a clear conscience!

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Fugh, Justina
Sent: Monday, March 11, 2019 4:00 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: We need your help, please

Hi Anna,

During the shutdown, I was permitted to do "incidental" work while I waited for people to call me with ethics questions. I used that time to go over some financial disclosure reports, including yours. I returned the report to you on 1/10/19 and asked you one question (see below). Can you please open the file, resolve the question, and then send the report back to me so that we can certify it? Then you will be all ready for the filing that is due on May 15, 2019.

Comments of Reviewing Officials (not publicly displayed on report):

PART	#	REFERENCE	COMMENT
N/A	N/A	General	(01/10/19, Fugh, Justina): Hi -- (b) (6), (b) (3) (A) [redacted]

Also, attached is a cautionary note about your assets, as well as a draft recusal statement for you to review and then issue. Please send me a pdf of the recusal, signed and dated on letterhead, for my files.

Thanks,

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

Dear Anna,

In (belatedly) reviewing your OGE-278 (Public Financial Disclosure Report) in INTEGRITY, we noticed that you reported owning certain interests that might be affected by the performance of your official duties. These assets appear to be over the regulatory threshold, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure to that your private interests (including your assets) do not conflict with your public duties. Be vigilant!

YOUR FINANCIAL INTEREST(S) OF CONCERN

We identified the following financial interest(s) that may be affected by the performance of your official duties and that exceed the regulatory exemption level for specific party matters at a minimum. This does not necessarily mean that you have a current conflict of interest, but we want to flag the following for you:

- (b) (6) [redacted]

In fact, we note that your ownership interests in (b) (6) [redacted] is over the regulatory exemption level for participating in matters of general applicability, so you should reissue your recusal statement to make clear that you cannot participate in any particular matter involving the same sectors as those businesses (e.g., (b) (6) [redacted], etc.). We suggest that you revise and reissue your recusal statement to address (b) (6) [redacted] which is now over the threshold for particular matters of general applicability. As a reference, I have attached the last signed recusal we have on file for you.

Regulatory Exemption Levels

There are different regulatory exemption levels, depending on the type of particular matter. You can still participate if you own less than the levels below:

SPECIFIC PARTY MATTER e.g., an enforcement action against ABC Widget Company	MATTER OF GENERAL APPLICABILITY e.g., working on a rulemaking that affects all widget manufacturers
≤$15,000 aggregate in ABC Widget Co. ≤$25,000 aggregate for any affected non-parties (e.g., DEF Widget Corp. which manufactures a similar product)	≤$25,000 aggregate in any one widget maker (e.g., ABC Widget Corp. or DEF Widget Corp.) ≤$50,000 aggregate in all affected parties (all widget makers)

Don't forget that you have to add together your own ownership interest and any imputed interest. You also have to aggregate how many assets you own in the same sector.

EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.

EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

Why Do We Raise Concerns?

A criminal statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that affects any of your own interests or any imputed interest (e.g., spouse or dependent children). Your interests include not only ownership interests (e.g., stock, bonds, mutual funds) but also the interests of outside entities (e.g., any organization in which you are serving as an officer, director, or trustee) and prospective employers (any entity with which you are seeking future employment). So you can't participate in any particular matter that will have a direct and predictable effect on your financial interest.

The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

What is a particular matter?

A "particular matter" involves any deliberation, decision or action and that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

What is "personal and substantial" participation?

Personal participation means that you were personally involved in the matter or that you directed or controlled a subordinate's participation. Substantial participation means that your involvement in the matter was of significance, which includes decision-making, review or recommendation as to an action being taken, signing or approving a final document, and/or participating in a final decision briefing.

What is a "direct and predictable" effect on a financial interest?

The effect must be direct and predictable and not speculative (though the actual dollar amount does not need to be ascertained). There must be close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.

What to do if you're worried about a conflict

If you are concerned that you have a conflict, contact OGC/Ethics immediately. We will go over the available options for you. Typically, potential conflict of interests are resolved in one of the following ways:

1) Don't participate. This means that you do not participate in the matter at all, including attending meetings, receiving briefings or being copied on substantive documents. We recommend that you document your recusal in writing, with a copy to OGC/Ethics.

2) Divest entirely or get below the regulatory threshold. You can either sell outright on your own or, if the sale will result in a tax liability for capital gains, then you may instead contact OGC/Ethics for a "Certificate of Divestiture" before you sell. This will enable you to defer capital gains tax, but you have to ask OGC/Ethics for assistance before you divest.

3) Ask for a waiver. Only the Agency's Designated Agency Ethics Official (DAEO) in OGC is authorized to waive the prohibition of 18 U.S.C. §208(a) where the interest is "not so substantial as to be deemed likely to affect the integrity of services which the Government may expect." OGC must consult with another federal agency before issuing a waiver, which are rarely granted.

* * * * *

If you need more information or advice, feel free to contact OGC/Ethics at ethics@epa.gov . We will be happy to assist you.

From: Fugh, Justina
To: Ross, Margaret; Clarke, Victoria
Subject: last message from Anna Lowitt
Date: Tuesday, June 11, 2019 3:56:44 PM

Plus her recusal note …

From: Lowit, Anna
Sent: Friday, April 12, 2019 3:52 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: RE: Please respond ASAP

Hey, on the (b) (6) [redacted] in other years to be reported. (and note, it probably won't make the trigger for the report due in May either, so it will disappear again).

Fugh, Justina Comment:
January 10th 2019, 3:54:50 pm EST

Hi -- (b) (6), (b) (3) (A) [redacted]

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Fugh, Justina
Sent: Wednesday, April 03, 2019 5:18 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: Please respond ASAP

Anna,

PLEASE come to closure on your CY 2017 report! Then you can start your CY 2018 report (that is due May 15, 2019) with a clear conscience!

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Fugh, Justina
Sent: Monday, March 11, 2019 4:00 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: We need your help, please

Hi Anna,

During the shutdown, I was permitted to do "incidental" work while I waited for people to call me with ethics questions. I used that time to go over some financial disclosure reports, including yours. I returned the report to you on 1/10/19 and asked you one question (see below). Can you please open the file, resolve the question, and then send the report back to me so that we can certify it? Then you will be all ready for the filing that is due on May 15, 2019.

Comments of Reviewing Officials (not publicly displayed on report):

PART	#	REFERENCE	COMMENT
N/A	N/A	General	(01/10/19, Fugh, Justina): Hi -- (b) (6), (b) (3) (A) [redacted].

Also, attached is a cautionary note about your assets, as well as a draft recusal statement for you to review and then issue. Please send me a pdf of the recusal, signed and dated on letterhead, for my files.

Thanks,

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Anna
To: Fugh, Justina; Sisco, Debby
Cc: Ross, Margaret
Subject: RE: Please respond ASAP
Date: Thursday, April 4, 2019 8:06:21 AM

Hi Justina
What do you need me to do with these files? Is it possible to add some clarity in the cautionary note about when I'm able to review chemical specific documents (e.g., chemical risk evaluations or provide chemical specific guidance)? Does it depend on the company, the sector, something else?
Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Fugh, Justina
Sent: Wednesday, April 03, 2019 5:18 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: Please respond ASAP

Anna,
PLEASE come to closure on your CY 2017 report! Then you can start your CY 2018 report (that is due May 15, 2019) with a clear conscience!
Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Fugh, Justina
Sent: Monday, March 11, 2019 4:00 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: We need your help, please

Hi Anna,
During the shutdown, I was permitted to do "incidental" work while I waited for people to call me with ethics questions. I used that time to go over some financial disclosure reports, including yours. I returned the report to you on 1/10/19 and asked you one question (see below). Can you please open the file, resolve the question, and then send the report back to me so that we can certify it? Then you will be all ready for the filing that is due on May 15, 2019.
Comments of Reviewing Officials (not publicly displayed on report):

PART	#	REFERENCE	COMMENT
N/A	N/A	General	(01/10/19, Fugh, Justina): Hi -- (b) (6), (b) (3) (A) [redacted]

Also, attached is a cautionary note about your assets, as well as a draft recusal statement for you to review and then issue. Please send me a pdf of the recusal, signed and dated on letterhead, for my files.
Thanks,
Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Anna
To: Clarke, Victoria
Subject: FW: Please respond ASAP
Date: Tuesday, June 11, 2019 3:49:19 PM

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Lowit, Anna
Sent: Friday, April 12, 2019 3:52 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: RE: Please respond ASAP

Hey, on the (b) (6) in other years to be reported. (and note, it probably won't make the trigger for the report due in May either, so it will disappear again).

Fugh, Justina Comment:
January 10th 2019, 3:54:50 pm EST

Hi --(b) (6), (b) (3) (A)

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Fugh, Justina
Sent: Wednesday, April 03, 2019 5:18 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: Please respond ASAP

Anna,
PLEASE come to closure on your CY 2017 report! Then you can start your CY 2018 report (that is due May 15, 2019) with a clear conscience!
Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Fugh, Justina
Sent: Monday, March 11, 2019 4:00 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: We need your help, please

Hi Anna,
During the shutdown, I was permitted to do "incidental" work while I waited for people to call me with ethics questions. I used that time to go over some financial disclosure reports, including yours. I returned the report to you on 1/10/19 and asked you one question (see below). Can you please open the file, resolve the question, and then send the report back to me so that we can certify it? Then you will be all ready for the filing that is due on May 15, 2019.
Comments of Reviewing Officials (not publicly displayed on report):

PART	#	REFERENCE	COMMENT
N/A	N/A	General	(01/10/19, Fugh, Justina): Hi --(b) (6), (b) (3) (A)

(b) (6), (b) (3) (A) [redacted]

Also, attached is a cautionary note about your assets, as well as a draft recusal statement for you to review and then issue. Please send me a pdf of the recusal, signed and dated on letterhead, for my files.

Thanks,

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Clarke, Victoria
To: Ross, Margaret
Cc: Fugh, Justina
Subject: RE: Please respond ASAP
Date: Tuesday, June 11, 2019 3:53:00 PM

This is done.
Victoria Clarke
Attorney-Advisor
U.S. Environmental Protection Agency
Office of General Counsel
Washington, D.C. |7348 WJCN
EPA Office: 202-564-1149
EPA Cell: 202-336-9101

From: Clarke, Victoria
Sent: Tuesday, June 11, 2019 3:36 PM
To: Ross, Margaret <Ross.Margaret@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: RE: Please respond ASAP

Yep! I'll add her to my list.
Victoria Clarke
Attorney-Advisor
U.S. Environmental Protection Agency
Office of General Counsel
Washington, D.C. |7348 WJCN
EPA Office: 202-564-1149
EPA Cell: 202-336-9101

From: Ross, Margaret
Sent: Tuesday, June 11, 2019 3:35 PM
To: Clarke, Victoria <clarke.victoria@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: FW: Please respond ASAP

It appears that Anna Lowit still has not come to closure on her 2018 report. The report is with her, and there are pending questions, and she hasn't been into the report since Justina returned it to her on 1/10/19.

Can I request a Victoria follow up?

Margaret Ross | Ethics Officer | Office of General Counsel | US EPA | William Jefferson Clinton Federal Building Room 4310A North | Wash ngton, DC 20460 (for ground deliveries: 20004) | phone 202-564-3221 |work cell 202-527-0432

From: Fugh, Justina
Sent: Wednesday, April 3, 2019 5:18 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: Please respond ASAP

Anna,

PLEASE come to closure on your CY 2017 report! Then you can start your CY 2018 report (that is due May 15, 2019) with a clear conscience!

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Fugh, Justina
Sent: Monday, March 11, 2019 4:00 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Ross, Margaret <Ross.Margaret@epa.gov>
Subject: We need your help, please

Hi Anna,

During the shutdown, I was permitted to do "incidental" work while I waited for people to call me with ethics questions. I used that time to go over some financial disclosure reports, including yours. I returned the report to you on 1/10/19 and asked you one question (see below). Can you please open the file, resolve the question, and then send the report back to me so that we can certify it? Then you will be all ready for the filing that is due on May 15, 2019.

Comments of Reviewing Officials (not publicly displayed on report):

PART	#	REFERENCE	COMMENT

(01/10/19, Fugh, Justina): Hi -- (b) (6), (b) (3) (A)

N/A	N/A	General	(b) (6), (b) (3) (A) [redacted]

Also, attached is a cautionary note about your assets, as well as a draft recusal statement for you to review and then issue. Please send me a pdf of the recusal, signed and dated on letterhead, for my files.

Thanks,

Justina

Justina Fugh | Director, Ethics Off ce | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Anna
To: Griffo, Shannon
Subject: RE: Request
Date: Friday, January 28, 2022 2:45:16 PM
Attachments: image001.png

Thanks for the update. Have a good weekend.
Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Friday, January 28, 2022 2:28 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: Request

Hi Anna,
Thanks for sending me all the additional information. I've been swamped with an upcoming February 1st regulatory deadline – our annual report is due to the Office of Government Ethics. But I'll be able to turn my attention to all this as soon as we submit the report. I'll reach out with any questions once I review everything, and I'll get you a summary of our meeting, your ethics obligations, and your potential OPPT projects as soon as I can.
Have a great weekend!
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, January 27, 2022 11:06 AM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: FW: Request

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Hartman, Mark <Hartman.Mark@epa.gov>
Sent: Thursday, January 27, 2022 10:55 AM

To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: RE: Request
Actually there is more. This may be more helpful to OGC.

From: Hartman, Mark
Sent: Thursday, January 27, 2022 10:46 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: FW: Request
Not sure this is what OGC needs. We don't have much on market share by COU at this point for the next 20. There are some emerging data needs/read across issues around PAD where I think you could really help so we can try to find more info if this is not sufficient.

From: Selby-Mohamadu, Yvette <Selby-Mohamadu.Yvette@epa.gov>
Sent: Wednesday, January 26, 2022 10:57 AM
To: Hartman, Mark <Hartman.Mark@epa.gov>
Cc: Blair, Susanna <Blair.Susanna@epa.gov>
Subject: RE: Request
Here are the two tables. Please let me know if you have additional questions.
Thanks,
Yvette

From: Hartman, Mark <Hartman.Mark@epa.gov>
Sent: Tuesday, January 25, 2022 4:13 PM
To: Selby-Mohamadu, Yvette <Selby-Mohamadu.Yvette@epa.gov>
Cc: Blair, Susanna <Blair.Susanna@epa.gov>
Subject: Request
Phthalic anhydride and trans 1,2-dichloroethylene scopes…..can someone pull out the use (PV etc.) and COU descriptions from the scopes for these two and dump them in a separate file? For a recusal question. Thanks.
Mark A. Hartman
Deputy Director
Office of Pollution Prevention and Toxics
(202) 564-0985

From: Mosley, Ferne
To: Lowit, Anna
Subject: RE: transaction report
Date: Thursday, February 11, 2021 12:42:00 PM
Attachments: image001.png

Yes, that's fine.

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, February 11, 2021 12:42 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Will do. Is 1:15 ok?

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:42 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

OK, Anna – you can call me at 202-306-2998.

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, February 11, 2021 12:32 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Sounds fine, but sorry to be a pest but I'd like a quick call to make sure I include the information needed in the email.

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs

US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:26 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Anna, if you can just briefly explain the circumstances in an email to Justina, that will be sufficient as the waiver request must be in writing by regulation.

Ferne

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, February 11, 2021 12:20 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Thanks for the follow up. Can we have a call to talk about the waiver? We were not notified of this until January.

Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:13 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: RE: transaction report
Importance: High

OK, that helps. There is another issue - (b) (6) on 11/17/20 was not reported timely – e.g., *the earlier* of 30 days of notification of the transaction, or 45 days after the transaction took place. You filed the transaction report on 2/5/21. The latest due date of the transaction was 1/1/21 using the 45 day reporting period. With a 30 day grace period before the fine is imposed, you would have had to file the report no later than 1/31/21 to avoid the fee.

Because the report was not filed until 2/5/21, there is an automatic $200 late filing fee payable to the U.S. Treasury. If you wish to request a waiver of the late filing fee by describing extraordinary circumstances that caused you to report the transaction late, you can submit a written request to Justina Fugh, the EPA Alternate Designated Agency Ethics Official, via email at fugh.justina@epa.gov, **by February 15, 2021**. Otherwise, Ms. Fugh will advise you of where to send the check.
Sincerely, Ferne

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Wednesday, February 10, 2021 7:24 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Subject: Re: transaction report

This is the terminology used to describe the transactions in our bank statements.
(b) (6) [redacted]
Hope this helps.
Anna

Sent from my iPhone

> On Feb 10, 2021, at 10:50 AM, Mosley, Ferne <mosley.ferne@epa.gov> wrote:
>
> Hi, Anna – I'm reviewing your recent transaction report. You reported a transaction with a date of 11/17/2020:
> <image001.png>
> In the endnote, you stated that this was a "(b) (6), (b) (3) (A) ." I'm not sure what that means – was this stock actually an "exchange" from another stock holding to this stock? If so, both parts of the exchange need to be identified, e.g., what was the prior stock.
> The same is true for the (b) (6), (b) (3) (A) Please clarify.
> <image002.png>
> *Thank you,*
> *Ferne*
> *Ferne L. Mosley, Attorney-Advisor*
> U.S. Environmental Protection Agency
> Ethics Office/Office of General Counsel
> William Jefferson Clinton Building North, Room 4113A
> 1200 Pennsylvania Ave, NW
> Washington, DC 20460
> (202) 564-8046 (desk)
> (202) 306-2998 (mobile)
> mosley.ferne@epa.gov

From: Fugh, Justina
To: Lowit, Michael; Lowit, Anna
Cc: Mosley, Ferne
Subject: RE: transaction report
Date: Tuesday, February 23, 2021 6:58:00 PM
Attachments: image001.png

Hi Michael,

The obligation to report the transaction is Anna's, not yours, though it's quite refreshing to see that you consider it your shared responsibility. It's frankly unusual for us to work with the spouse of the filer. I'll permit it here only because you are also an EPA employee. It's important for Anna – and you – to understand the reporting rule, which is NOT as you expressed it. As a public financial disclosure filer, Anna is required to transactions over $1000 – including, yes, exchanges – within 30 days after receiving notice *but not later than 45 days after the trade itself.* 5 CFR 2634.201(f). So don't concentrate on the 30 days' notice. The obligation is that the filer must report the transactions within 45 days of occurrence, irrespective of notification date.

I'll notify Anna directly of my decision about her waiver of the late fee.

Justina

Justina Fugh | Director Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North William Jefferson Clinton Federal Building | Washington DC 20460 (for ground deliveries use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Michael <Lowit.Michael@epa.gov>
Sent: Tuesday, February 23, 2021 5:11 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Mosley, Ferne <mosley.ferne@epa.gov>
Subject: RE: transaction report

Hi Justina,

It was actually less than 4 weeks. I want to clarify an earlier email from Anna, which I didn't notice, but see that she misunderstood what I had told her. The statement reflects the account status on Dec 31st. However, it is typically mid-month when I receive a quarterly statement by the time they actually create and send it out. My recollection is that my receipt of the statement was delayed beyond mid-month this past quarter due to the delays that everyone was experiencing with the US mail over the last several months. My understanding is that we have 30 days to report from when we were notified, which we were within.

Also please take into consideration that this was not a purchase but a (b) (6) Given this was not a purchase and it was not clear to me if this qualified as an "exchange", it wasn't clear to me if it needed to be included as a periodic transaction, but we decided to report it out of due diligence. Further, we reported the value based on 12/31/20 (b) (6)), not the amount that was reported in the activity section of my statement, which is what I have to look at for transactions. It showed the transaction being reported as (b) (6) on 11/17/20, below the $1k threshold. Unfortunately, I reasonably thought this was the value at the time of the transaction and I did not immediately realize that the reported transaction amount was the tax cost based on (b) (6). But again, once I realized this, we reported the reorganization based on the value on 12/31/20 out of due diligence.

Anna has always been on time with reporting and we attempted to comply with the reporting requirements in good faith.

Thanks for your consideration of a waiver.

Michael

From: Fugh, Justina <Fugh.Justina@epa.gov>
Sent: Monday, February 22, 2021 10:47 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Lowit, Michael <Lowit.Michael@epa.gov>; Mosley, Ferne <mosley.ferne@epa.gov>
Subject: RE: transaction report

Hi Anna,

But what is your explanation for why you did not file the transaction report when you received the statement? Why did you wait another nearly 4 weeks to file the periodic transaction report?

Justina

Justina Fugh | Director Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North William Jefferson Clinton Federal Building | Washington DC 20460 (for ground deliveries use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Michael <Lowit.Michael@epa.gov>
Sent: Wednesday, February 17, 2021 4:10 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Mosley, Ferne <mosley.ferne@epa.gov>
Subject: RE: transaction report

Hi Justina,

That is correct, we only get quarterly statements.

Thanks,

Michael

From: Fugh, Justina <Fugh.Justina@epa.gov>
Sent: Wednesday, February 17, 2021 3:48 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Anna,

I don't quite understand why the bank didn't tell you until January 1 about a transaction that occurred in November 2020. Is it that you get only quarterly statements from the bank?

Justina

Justina Fugh | Director Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North William Jefferson Clinton Federal Building | Washington DC 20460 (for ground deliveries use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Friday, February 12, 2021 2:14 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Hi Ferne & Justina

I am requesting a waiver for the $200 fine mentioned below.

The bank statement for the (b) (6) is dated Jan 1, 2021 and we received it in the mail approximately a week later. We were unaware of the (b) (6) until we received the bank statement. This is reason for the tardiness in the report filing. We did report the purchase within 30 days our knowledge.

Thanks for the consideration of this waiver request.

Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:26 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Anna, if you can just briefly explain the circumstances in an email to Justina, that will be sufficient as the waiver request must be in writing by regulation.

Ferne

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel

William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, February 11, 2021 12:20 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Thanks for the follow up. Can we have a call to talk about the waiver? We were not notified of this until January.
Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:13 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: RE: transaction report
Importance: High

OK, that helps. There is another issue - (b) (6) [redacted] on 11/17/20 was not reported timely – e.g., *the earlier* of 30 days of notification of the transaction, or 45 days after the transaction took place. You filed the transaction report on 2/5/21. The latest due date of the transaction was 1/1/21 using the 45 day reporting period. With a 30 day grace period before the fine is imposed, you would have had to file the report no later than 1/31/21 to avoid the fee.

Because the report was not filed until 2/5/21, there is an automatic $200 late filing fee payable to the U.S. Treasury. If you wish to request a waiver of the late filing fee by describing extraordinary circumstances that caused you to report the transaction late, you can submit a written request to Justina Fugh, the EPA Alternate Designated Agency Ethics Official, via email at fugh.justina@epa.gov, **by February 15, 2021**. Otherwise, Ms. Fugh will advise you of where to send the check.
Sincerely, Ferne

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Wednesday, February 10, 2021 7:24 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Subject: Re: transaction report

This is the terminology used to describe the transactions in our bank statements.

(b) (6) [redacted]

Hope this helps.
Anna

Sent from my iPhone

> On Feb 10, 2021, at 10:50 AM, Mosley, Ferne <mosley.ferne@epa.gov> wrote:
>
> Hi, Anna – I'm reviewing your recent transaction report. You reported a transaction with a date of 11/17/2020:
> <image001.png>
> In the endnote, you stated that this was a "(b) (6), (b) (3) (A) ." I'm not sure what that means – was this stock actually an "exchange" from another stock holding to this stock? If so, both parts of the exchange need to be identified, e.g., what was the prior stock.
> The same is true for the (b) (6), (b) (3) (A) ." Please clarify.
> <image002.png>
> *Thank you,*
> *Ferne*
> *Ferne L. Mosley, Attorney-Advisor*
> U.S. Environmental Protection Agency
> Ethics Office/Office of General Counsel
> William Jefferson Clinton Building North, Room 4113A
> 1200 Pennsylvania Ave, NW
> Washington, DC 20460
> (202) 564-8046 (desk)
> (202) 306-2998 (mobile)
> mosley.ferne@epa.gov

From: Fugh, Justina
To: Lowit, Anna
Cc: Mosley, Ferne
Subject: RE: transaction report
Date: Tuesday, February 23, 2021 9:16:00 PM
Attachments: image001.png

Anna,

As a public financial disclosure filer, you have a legal obligation to report any purchase, sale, or exchange of stocks, bonds, commodity futures, and other forms of securities that occur during the year when the amount involved in the transaction exceeds $1000. 5 C.F.R. § 2634.309. You must file a transaction report "within 30 days of receiving notification of a covered transaction, *but not later than 45 days afer such transaction* (emphasis added)." 5 C.F.R. § 2634.201(f). You and your spouse readily admit that a transaction occurred in November 2020 but that you did not notify my office until 2/5/21, which was 80 days after the transaction occurred.

To be clear, any late reporting results, by law, in the assessed fine. The law does permit filers to seek a waiver of that automatic late fee, if the "delay in filing was caused by extraordinary circumstances." 5 C.F.R. § 2634.704(b). The circumstances you and your spouse assert are:

- You did not initiate the transaction;
- You do not receive monthly statements but rather only quarterly statements;
- You did not realize that the exchange had occurred until you looked at the quarterly statement dated 12/31/20 that you did not receive until at least one week later;
- You did not realize that an exchange was in fact reportable;
- You initially misread the statement, believing that the exchange involved an amount less than the reporting threshold; and
- You incorrectly believed that your filing requirement was 30 days after receipt of the statement.

I will grant the late fee waiver this one time, based only on the fact that you did not initiate the exchange. The other points are not particularly compelling. You did not expect the transaction and did not even know about it until you received notification in the 12/31/20 statement. To be clear, that statement was generated 44 days after the exchange itself occurred, so even when you received the statement in January, you were already subject to the late fee. As I said, though, I'll grant the waiver this time.

Thanks for explaining how this situation arose, and please consider changing your notification from your broker from quarterly to monthly to avoid unhappy surprises in the future.

Justina

Justina Fugh | Director Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North William Jefferson Clinton Federal Building | Washington DC 20460 (for ground deliveries use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Friday, February 12, 2021 2:14 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Hi Ferne & Justina

I am requesting a waiver for the $200 fine mentioned below.

The bank statement for (b) (6) is dated Jan 1, 2021 and we received it in the mail approximately a week later. We were unaware of the (b) (6) until we received the bank statement. This is reason for the tardiness in the report filing. We did report the purchase within 30 days our knowledge.

Thanks for the consideration of this waiver request.

Anna

Anna B. Lowit

Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency

w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:26 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Anna, if you can just briefly explain the circumstances in an email to Justina, that will be sufficient as the waiver request must be in writing by regulation.

Ferne

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Thursday, February 11, 2021 12:20 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>; Lowit, Michael <Lowit.Michael@epa.gov>
Subject: RE: transaction report

Thanks for the follow up. Can we have a call to talk about the waiver? We were not notified of this until January.

Anna

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Mosley, Ferne <mosley.ferne@epa.gov>
Sent: Thursday, February 11, 2021 12:13 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: RE: transaction report
Importance: High

OK, that helps. There is another issue - the (b) (6) on 11/17/20 was not reported timely – e.g., *the earlier* of 30 days of notification of the transaction, or 45 days after the transaction took place. You filed the transaction report on 2/5/21. The latest due date of the transaction was 1/1/21 using the 45 day reporting period. With a 30 day grace period before the fine is imposed, you would have had to file the report no later than 1/31/21 to avoid the fee.

Because the report was not filed until 2/5/21, there is an automatic $200 late filing fee payable to the U.S. Treasury. If

you wish to request a waiver of the late filing fee by describing extraordinary circumstances that caused you to report the transaction late, you can submit a written request to Justina Fugh, the EPA Alternate Designated Agency Ethics Official, via email at fugh.justina@epa.gov, **by February 15, 2021**. Otherwise, Ms. Fugh will advise you of where to send the check.
Sincerely, Ferne

Ferne L. Mosley, Attorney-Advisor
U.S. Environmental Protection Agency
Ethics Office/Office of General Counsel
William Jefferson Clinton Building North, Room 4113A
1200 Pennsylvania Ave, NW
Washington, DC 20460
(202) 564-8046 (desk)
(202) 306-2998 (mobile)
mosley.ferne@epa.gov

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Wednesday, February 10, 2021 7:24 PM
To: Mosley, Ferne <mosley.ferne@epa.gov>
Subject: Re: transaction report

This is the terminology used to describe the transactions in our bank statements.
(b) (6)
[redacted]
Hope this helps.
Anna

Sent from my iPhone

> On Feb 10, 2021, at 10:50 AM, Mosley, Ferne <mosley.ferne@epa.gov> wrote:
>
> Hi, Anna – I'm reviewing your recent transaction report. You reported a transaction with a date of 11/17/2020:
> <image001.png>
> In the endnote, you stated that this was a "(b) (6), (b) (3) (A) ." I'm not sure what that means – was this stock actually an "exchange" from another stock holding to this stock? If so, both parts of the exchange need to be identified, e.g., what was the prior stock.
> The same is true for the (b) (6), (b) (3) (A) ." Please clarify.
> <image002.png>
> *Thank you,*
> *Ferne*
> *Ferne L. Mosley, Attorney-Advisor*
> U.S. Environmental Protection Agency
> Ethics Office/Office of General Counsel
> William Jefferson Clinton Building North, Room 4113A
> 1200 Pennsylvania Ave, NW
> Washington, DC 20460
> (202) 564-8046 (desk)
> (202) 306-2998 (mobile)
> mosley.ferne@epa.gov

From: Griffo, Shannon
To: Lowit, Anna
Subject: RE: Updated recusal
Date: Tuesday, September 28, 2021 3:36:00 PM
Attachments: image002.jpg
image005.jpg
image007.jpg
image008.jpg
image009.jpg

Hi Anna,
Of course. I should be around Monday-Thursday of next week, so just let me know a good time or send me a scheduler (my calendar is up to date).
Thanks,
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, September 28, 2021 2:57 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: FW: Updated recusal
Hey Shannon
Do you have a few minutes early next week? I could use some input from you.
Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Tuesday, September 28, 2021 2:51 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: Updated recusal
(b) (6), (b) (5) [redacted].

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, September 28, 2021 2:44 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
Subject: RE: Updated recusal
One more question. (b) (6), (b) (5) [redacted]
Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Tuesday, September 28, 2021 9:57 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
Subject: RE: Updated recusal

			(b) (6), (b) (5) [redacted]
[redacted]	[redacted]	[redacted]	• [redacted]
[redacted]	[redacted]	[redacted]	• [redacted] • [redacted] • [redacted] • [redacted]

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, September 28, 2021 9:09 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: Updated recusal

Thanks so much.
Is it possible to (b) (5) [redacted] ?
Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Tuesday, September 28, 2021 8:31 AM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: FW: Updated recusal

See below for (b) (6), (b) (5) [redacted] .

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Tuesday, September 28, 2021 8:26 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal

Anita and Steve,
Here is the (b) (6), (b) (5) [redacted] . I thought they would but I just wanted to make sure.

(b) (6), (b) (5) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
	[redacted]	

(b) (6), (b) (5)

[redacted]

Aline

****

Aline Heffernan
Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

From: Heffernan, Aline
Sent: Monday, September 27, 2021 7:40 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal

Sounds good.

****

Aline Heffernan
Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Monday, September 27, 2021 7:34 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal

No rush – sometime next week?

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Monday, September 27, 2021 7:30 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal

Yes, when do you need it by?

****

Aline Heffernan
Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Monday, September 27, 2021 7:28 AM
To: Weiss, Steven <Weiss.Steven@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>
Subject: FW: Updated recusal

Good morning,

Aline, can you please create a list of (b) (6), (b) (5) [redacted]

Thanks,

Anita

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Friday, September 24, 2021 3:24 PM
To: Pease, Anita <Pease.Anita@epa.gov>
Subject: FW: Updated recusal

Hey Anita

Could you do me a favor? Can you have someone do a (b) (6), (b) (5) [redacted]

Thanks

Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Lowit, Anna
Sent: Thursday, September 2, 2021 9:52 AM
To: Messina, Edward <Messina.Edward@epa.gov>; Richard Keigwin (Keigwin.Richard@epa.gov) <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Jewell, Shannon <jewell.shannon@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Anita Pease (Pease.Anita@epa.gov) <Pease.Anita@epa.gov>
Cc: Griffo, Shannon <Griffo.Shannon@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Subject: Updated recusal

Ed and others

With help from OGC, I've updated my recusal. I have gotten some clarity from OGC on support for OPPT.

From Shannon: "Based on our discussion, and then my follow-up conversation with Jeff Dawson about the PFAS work, I've learned that these are really matters of general science and determined there is no distinct effect on one industry. The PFAS work involves studies for test orders, and the TSCA-related project involves work on a database of toxicity information. So for our conflicts analysis purposes, we focus on the fact that a multitude of sectors could be affected, which makes it too broad of a group to qualify as a "distinct and identifiable class." And for those reasons, we've

determined that these are broader “matters” and not particular matters of general applicability.” So, it appears that I am OK to support the science discussion on-going on the PFAS test orders and the new ORD project to develop new high thru put data and computational models to support industrial chemicals.

Please let me know if you have any Qs.

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 703-308-4135
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
MC7501PY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Fugh, Justina
To: Griffo, Shannon
Subject: assorted emails -- Anna Lowit
Date: Sunday, July 25, 2021 10:11:15 PM
Attachments: RE transaction report.msg
CORRECTED Cautionary note about your financial interests .msg
RE CORRECTED Cautionary note about your financial interests .msg
RE transaction report.msg
We need your help please.msg

Hi,

Here are the emails related to Lowit, including the exchanges about the recusal statement. Just so you know, her husband also works at EPA, and I granted her a waiver of a late 278T earlier this year.

Justina

Justina Fugh (she/her) | Director, Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From:	Fugh, Justina
To:	Griffo, Shannon
Subject:	RE: assorted emails -- Anna Lowit
Date:	Tuesday, July 27, 2021 5:17:58 PM

For Anna, does she (b) (6), (b) (5)

Justina

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Tuesday, July 27, 2021 3:09 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: RE: assorted emails -- Anna Lowit

Let's also talk about Anna tomorrow because (b) (6), (b) (5)

Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Fugh, Justina <Fugh.Justina@epa.gov>
Sent: Sunday, July 25, 2021 10:11 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: assorted emails -- Anna Lowit

Hi,

Here are the emails related to Lowit, including the exchanges about the recusal statement. Just so you know, her husband also works at EPA, and I granted her a waiver of a late 278T earlier this year.

Justina

Justina Fugh (she/her) | Director, Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Sisco, Debby
To: Lowit, Anna
Cc: Keigwin, Richard; Fort, Daniel
Subject: RE: Recusal and OPPT"s request for assistance on alternative testing
Date: Wednesday, March 22, 2017 1:43:32 PM
Attachments: ALowit Recusal_2016.pdf

Anna,

You have been asked to assist our colleagues in OPPT to write a document about how they will implement alternative testing (i.e., non-animal studies) into their risk assessment processes under the new Lautenberg Act. As you and Dan have discussed, this would not be a particular matter involving specific parties, but rather a matter of general applicability. The testing requirements for substances for risk assessment processes under the Toxic Substances Control Act (TSCA) would likely have some effect on many sectors, including some or all of those on your recusal list.

As indicated in your recusal (attached), "…if a particular matter affects a combination of sectors, including the ones listed below, then [you would] not have a financial conflict of interest". Thus, I do not believe you would have a conflict of interest if you help OPPT with that project.

Debby Sisco
Office of Pesticide Programs (7501P)
Ethics Officer and Special Assistant to the Director
Room 12651 Potomac Yard South (office: 703 308-8121; cell: 571 317-4823)

From: Lowit, Anna
Sent: Tuesday, March 21, 2017 3:42 PM
To: Sisco, Debby <Sisco.Debby@epa.gov>
Cc: Keigwin, Richard <Keigwin.Richard@epa.gov>
Subject: FW: Recusal

Debby

I just had a skype 'conversation' with Dan Fort about a Q I have on this & he said I should ask you…….

As part of the new requirements under the new Lautenberg Act, our toxics colleagues have to write a document about how they are going implement alternatives (ie, non-animal studies) into their risk assessment processes. At SOT last week, I was approached by Gina Scarano in OPPT-RAD about providing input into this document. Since the document would not be targeted to any specific company or sector, seemed OK to me (based on conversations with Dan last summer). This is what he wrote in skype……

If you have a signed recusal, send me an electronic copy. That being said, ***this isn't a specific party matter and it doesn't seem to be in any of the individual sectors that would be a problem***. You might want to consult with Debbie Sisco in your office to be absolutely sure.

Thoughts???

No hurry.

Anna B. Lowit, Ph.D.
Senior Science Advisor
Immediate Office
Office of Pesticide Programs, USEPA
w: 703-308-4135
c: 703-258-4209

From: Lowit, Anna
Sent: Thursday, June 16, 2016 1:50 PM
To: Housenger, Jack <Housenger.Jack@epa.gov>; Sisco, Debby <Sisco.Debby@epa.gov>; Fort, Daniel <Fort.Daniel@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Cc: Dinkins, Darlene <Dinkins.Darlene@epa.gov>
Subject: Recusal

Hi Justina & Dan

Here is my signed recusal.

Anna

Anna B. Lowit, Ph.D.
Senior Science Advisor
Immediate Office
Office of Pesticide Programs, USEPA
w: 703-308-4135
c: 703-258-4209

From: Griffo, Shannon
To: Lowit, Anna
Subject: Updated draft recusal statement for OPPT
Date: Friday, September 9, 2022 9:34:00 AM
Attachments: Anna Lowit draft recusal statement OPPT September 2022.docx
Anna Lowit Asset Chart 2022.docx

Hi Anna,
Here is an updated draft recusal statement for your review. I also attached the asset chart I made based on your most recent Annual Report. This helps me keep track of your recusals and corresponds to my comments in the recusal.
Please take a look and let me know if you have any comments or concerns.
Thanks and have a great weekend!
Shannon

Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061

From: Clarke, Victoria
To: Lowit, Anna
Subject: Your 2020 Cautionary Note
Date: Monday, June 22, 2020 4:38:00 PM
Attachments: cautionary note for 2020 filing.docx

Hi Anna,
This is Victoria Clarke from OGC Ethics. I've reviewed and certified your 278, and have a cautionary note for you based on some of your holdings. You've likely received this note from us before, so there isn't anything to worry about. Please note that this doesn't mean you have a current or actual conflict of interest, we just flag this for you prospectively for your information. Knowledge is power.
Victoria
Victoria Clarke
Attorney-Advisor
U.S. Environmental Protection Agency
Office of General Counsel
Washington, D.C. |7348 WJCN
EPA Office: 202-564-1149
EPA Cell: 202-336-9101

Dear Anna,

In reviewing your OGE-278 (Public Financial Disclosure Report) in INTEGRITY, we noticed that you reported owning certain interests that might be affected by the performance of your official duties. These assets appear to be over the regulatory threshold, so we are sending you this cautionary letter to remind you to take appropriate steps to ensure that you do not have a conflict of interest. We are not concluding that you currently have a conflict of interest; rather, you should read the information below and contact an ethics official if you have any questions. Remember, it is your obligation to ensure to that your private interests (including your assets) do not conflict with your public duties. Be vigilant!

YOUR FINANCIAL INTEREST(S) OF CONCERN

We identified the following financial interest(s) that may be affected by the performance of your official duties and that exceed the regulatory exemption level for specific party matters at a minimum. This does not necessarily mean that you have a current conflict of interest, but we want to flag the following for you:

- (b) (6) [redacted]

In fact, we note that your ownership interests in (b) (6) [redacted] is over the regulatory exemption level for participating in matters of general applicability, so you should reissue your recusal statement to make clear that you cannot participate in any particular matter involving the same sectors as those businesses (e.g., (b) (6) [redacted]). We suggest that you revise and reissue your recusal statement to address (b) (6) [redacted] which is now over the threshold for particular matters of general applicability. As a reference, I have attached the last signed recusal we have on file for you.

Regulatory Exemption Levels

There are different regulatory exemption levels, depending on the type of particular matter. You can still participate if you own less than the levels below:

SPECIFIC PARTY MATTER e.g., an enforcement action against ABC Widget Company	MATTER OF GENERAL APPLICABILITY e.g., working on a rulemaking that affects all widget manufacturers
≤$15,000 aggregate in ABC Widget Co.	≤$25,000 aggregate in any one widget maker (e.g., ABC Widget Corp. or DEF Widget Corp.)

≤$25,000 aggregate for any affected non-parties (e.g., DEF Widget Corp. which manufactures a similar product)	≤$50,000 aggregate in all affected parties (all widget makers)

Don't forget that you have to add together your own ownership interest and any imputed interest. You also have to aggregate how many assets you own in the same sector.

> EXAMPLE: You own $8,000 worth of ABC Widget and your spouse also owns $8,000. You cannot direct your staff to participate in an event at ABC Widget offices because you own more than $15,000 in the company and cannot participate in any particular matter that involves or affects ABC Widget as a specific party.
>
> EXAMPLE: Your father-in-law passed away recently and bequeathed to your spouse shares in an oil and gas company worth $30,000. You can't work on a specific party matter involving that company and also now can't work on any rulemaking that affects all oil and gas companies.

Why Do We Raise Concerns?

A criminal statute, 18 U.S.C. §208(a), bars you from participating in any "particular matter" that affects any of your own interests or any imputed interest (e.g., spouse or dependent children). Your interests include not only ownership interests (e.g., stock, bonds, mutual funds) but also the interests of outside entities (e.g., any organization in which you are serving as an officer, director, or trustee) and prospective employers (any entity with which you are seeking future employment). So you can't participate in any particular matter that will have a direct and predictable effect on your financial interest.

The important point to remember here is that 18 U.S.C. §208(a) is a criminal statute. A knowing violation of this statute can result in criminal prosecution and penalties. It's important to understand the elements of the financial conflict of interest statute. You have to participate "personally and substantially" in a "particular matter" in order for there to be a conflict of interest, and there has to be a "direct and predictable" effect on your financial interests.

What is a particular matter?

A "particular matter" involves any deliberation, decision or action and that is focused on the interests of specific persons/organizations or any identifiable class of persons. It includes "specific party" matters (e.g., contracts, grants, assistance agreements, lawsuits, enforcement action, permits, licenses, audits) and matters of "general applicability" (e.g., rulemaking or policy matters) that distinctively affect a particular industry or identifiable class of persons.

What is "personal and substantial" participation?

Personal participation means that you were personally involved in the matter or that you directed or controlled a subordinate's participation. Substantial participation means that your involvement in the matter was of significance, which includes decision-making, review or recommendation as to an action being taken, signing or approving a final document, and/or participating in a final decision briefing.

What is a "direct and predictable" effect on a financial interest?

The effect must be direct and predictable and not speculative (though the actual dollar amount does not need to be ascertained). There must be close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.

What to do if you're worried about a conflict

If you are concerned that you have a conflict, contact OGC/Ethics immediately. We will go over the available options for you. Typically, potential conflict of interests are resolved in one of the following ways:

1) Don't participate. This means that you do not participate in the matter at all, including attending meetings, receiving briefings or being copied on substantive documents. We recommend that you document your recusal in writing, with a copy to OGC/Ethics.

2) Divest entirely or get below the regulatory threshold. You can either sell outright on your own or, if the sale will result in a tax liability for capital gains, then you may instead contact OGC/Ethics for a "Certificate of Divestiture" before you sell. This will enable you to defer capital gains tax, but you have to ask OGC/Ethics for assistance before you divest.

3) Ask for a waiver. Only the Agency's Designated Agency Ethics Official (DAEO) in OGC is authorized to waive the prohibition of 18 U.S.C. §208(a) where the interest is "not so substantial as to be deemed likely to affect the integrity of services which the Government may expect." OGC must consult with another federal agency before issuing a waiver, which are rarely granted.

* * * * *

If you need more information or advice, feel free to contact OGC/Ethics at ethics@epa.gov . We will be happy to assist you.

From: Clarke, Victoria
To: Lowit, Anna
Subject: RE: Your 2020 Cautionary Note
Date: Monday, June 22, 2020 4:56:00 PM

Oh! Yes, you will need an updated recusal to account for the new assets.
Victoria
Victoria Clarke
Attorney-Advisor
U.S. Environmental Protection Agency
Office of General Counsel
Washington, D.C. |7348 WJCN
EPA Office: 202-564-1149
EPA Cell: 202-336-9101

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Monday, June 22, 2020 4:54 PM
To: Clarke, Victoria <clarke.victoria@epa.gov>
Subject: RE: Your 2020 Cautionary Note
Do I need to update my recusal?

Anna B. Lowit
Senior Science Advisor
Immediate Office
Office of Pesticide Programs
US Environmental Protection Agency
w: +1 703-308-4135
c: +1 703-258-4209

From: Clarke, Victoria <clarke.victoria@epa.gov>
Sent: Monday, June 22, 2020 4:39 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Subject: Your 2020 Cautionary Note
Hi Anna,
This is Victoria Clarke from OGC Ethics. I've reviewed and certified your 278, and have a cautionary note for you based on some of your holdings. You've likely received this note from us before, so there isn't anything to worry about. Please note that this doesn't mean you have a current or actual conflict of interest, we just flag this for you prospectively for your information. Knowledge is power.
Victoria
Victoria Clarke
Attorney-Advisor
U.S. Environmental Protection Agency
Office of General Counsel
Washington, D.C. |7348 WJCN
EPA Office: 202-564-1149
EPA Cell: 202-336-9101

From: Lowit, Anna
To: Griffo, Shannon
Subject: FW: Updated recusal
Date: Wednesday, October 13, 2021 3:05:51 PM
Attachments: Citric Acid and Salts PWP-PID-2 - final signed.pdf
ADBAC FWP.pdf
image00001.png
image00001.png
Recusal.docx
image001.jpg
image003.jpg

Shannon
Here is the information we discussed. The 'recusal' file is a high level summary.
Let me know if this is what you need.
Anna

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs
Phone: +1 202-566-1254
Mobile: +1 703-258-4209
Email: lowit.anna@epa.gov
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1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Wednesday, October 13, 2021 2:19 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: FW: Updated recusal
See if this works. And thanks Aline!

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Wednesday, October 13, 2021 1:25 PM
To: Pease, Anita <Pease.Anita@epa.gov>
Subject: RE: Updated recusal
Anita,
I wrote a small blurb summarizing the use sites for both citric acid and the quats. Matt sent me the PWP for citric acid and I found the FWP for ADBAC (attached).
Let me know if you think I need more information or if this should be sufficient.
Thanks,
Aline

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Tuesday, October 12, 2021 2:59 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: Updated recusal
Of course. No hurry.

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Tuesday, October 12, 2021 2:49 PM
To: Pease, Anita <Pease.Anita@epa.gov>

Subject: RE: Updated recusal

Yes, I can pull something together. I'm running out of time for today but I'll work on it first thing tomorrow (if that's alright).

****

Aline Heffernan
Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Tuesday, October 12, 2021 2:03 PM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: FW: Updated recusal

Can you pull this together from the PWPs for the quats and citric acid?

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, October 12, 2021 1:52 PM
To: Pease, Anita <Pease.Anita@epa.gov>
Cc: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: Updated recusal

Anita & Aline

I just got off the phone with OGC. We had a good discussion but they need a little more info—probably out of the PWPs (hopefully). OGC needs to understand the types of industries that would be effected. For example, cleaning products for homeowners, hospitals/medical disinfectants, etc etc.) could you start with the Quats & Citric acid for now? So, I think a description of the uses from the PWP should suffice.

If this doesn't make sense, we could talk over the phone.

Thanks for your help.

Anna

Anna B. Lowit
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From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Thursday, September 30, 2021 2:27 PM
To: Lowit, Anna <Lowit.Anna@epa.gov>
Cc: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: Updated recusal

Anna,

See the attached file for the additional requested info re: your recusal. Hopefully, this provides what you need.

Thanks,

Anita

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, September 28, 2021 2:52 PM
To: Pease, Anita <Pease.Anita@epa.gov>
Cc: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: Re: Updated recusal
Great!

Sent from my iPhone

> On Sep 28, 2021, at 2:51 PM, Pease, Anita <Pease.Anita@epa.gov> wrote:
>
> (b) (6), (b) (5) [redacted].
>
> **From:** Lowit, Anna <Lowit.Anna@epa.gov>
> **Sent:** Tuesday, September 28, 2021 2:44 PM
> **To:** Heffernan, Aline <heffernan.aline@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
> **Subject:** RE: Updated recusal
> One more question. (b) (5), (b) (6) [redacted]?
> Anna
>
> <image001.jpg>
>
> **Anna B. Lowit**
> Senior Science Advisor
> US Environmental Protection Agency
> Office of Chemical Safety and Pollution Prevention
> Office of Pesticide Programs
> Phone: +1 202-566-1254
> Mobile: +1 703-258-4209
> Email: lowit.anna@epa.gov
> MC7501PY
> 1200 Pennsylvania Avenue, N.W.
> Washington, DC 20460
>
> **From:** Heffernan, Aline <heffernan.aline@epa.gov>
> **Sent:** Tuesday, September 28, 2021 9:57 AM
> **To:** Lowit, Anna <Lowit.Anna@epa.gov>; Pease, Anita <Pease.Anita@epa.gov>
> **Subject:** RE: Updated recusal
>
> | | | | |
> |---|---|---|---|
> | (b) (6), (b) (5) [redacted] | [redacted] | [redacted] | [redacted] |
> | [redacted] | [redacted] | [redacted] | [redacted] |
> | [redacted] | [redacted] | [redacted] | [redacted] |

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Tuesday, September 28, 2021 9:09 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>

Subject: RE: Updated recusal

Thanks so much.

Is it possible to (b) (5) [redacted] ?

Anna

<image003.jpg>

Anna B. Lowit
Senior Science Advisor
US Environmental Protection Agency
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Email: lowit.anna@epa.gov
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1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

From: Pease, Anita <Pease.Anita@epa.gov>

Sent: Tuesday, September 28, 2021 8:31 AM

To: Lowit, Anna <Lowit.Anna@epa.gov>

Subject: FW: Updated recusal

See below for (b) (6), (b) (5) [redacted] .

From: Heffernan, Aline <heffernan.aline@epa.gov>

Sent: Tuesday, September 28, 2021 8:26 AM

To: Pease, Anita <Pease.Anita@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>

Subject: RE: Updated recusal

Anita and Steve,

Here is the (b) (6), (b) (5) [redacted] .

I thought they would but I just wanted to make sure.

(b) (6), (b) (5) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

Aline

****

Aline Heffernan

Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

From: Heffernan, Aline
Sent: Monday, September 27, 2021 7:40 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal
Sounds good.
****
Aline Heffernan
Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

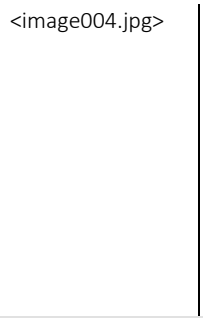
From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Monday, September 27, 2021 7:34 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal
No rush – sometime next week?

From: Heffernan, Aline <heffernan.aline@epa.gov>
Sent: Monday, September 27, 2021 7:30 AM
To: Pease, Anita <Pease.Anita@epa.gov>; Weiss, Steven <Weiss.Steven@epa.gov>
Subject: RE: Updated recusal
Yes, when do you need it by?
****
Aline Heffernan
Regulatory Advisor
Antimicrobials Division
Office of Pesticide Programs
(she/her)

From: Pease, Anita <Pease.Anita@epa.gov>
Sent: Monday, September 27, 2021 7:28 AM
To: Weiss, Steven <Weiss.Steven@epa.gov>; Heffernan, Aline <heffernan.aline@epa.gov>
Subject: FW: Updated recusal
Good morning,
Aline, can you please create a list of (b) (6), (b) (5) [redacted].
Thanks,
Anita

From: Lowit, Anna <Lowit.Anna@epa.gov>
Sent: Friday, September 24, 2021 3:24 PM

To: Pease, Anita <Pease.Anita@epa.gov>
Subject: FW: Updated recusal
Hey Anita
Could you do me a favor? Can you have someone do a (b) (6), (b) (5) [redacted]
Thanks
Anna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From: Lowit, Anna
Sent: Thursday, September 2, 2021 9:52 AM
To: Messina, Edward <Messina.Edward@epa.gov>; Richard Keigwin (Keigwin.Richard@epa.gov) <Keigwin.Richard@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Dinkins, Darlene <Dinkins.Darlene@epa.gov>; Jewell, Shannon <jewell.shannon@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Dawson, Jeffrey <Dawson.Jeff@epa.gov>; Anita Pease (Pease.Anita@epa.gov) <Pease.Anita@epa.gov>
Cc: Griffo, Shannon <Griffo.Shannon@epa.gov>; Fugh, Justina <Fugh.Justina@epa.gov>
Subject: Updated recusal
Ed and others
With help from OGC, I've updated my recusal. I have gotten some clarity from OGC on support for OPPT.
From Shannon: "Based on our discussion, and then my follow-up conversation with Jeff Dawson about the PFAS work, I've learned that these are really matters of general science and determined there is no distinct effect on one industry. The PFAS work involves studies for test orders, and the TSCA-related project involves work on a database of toxicity information. So for our conflicts analysis purposes, we focus on the fact that a multitude of sectors could be affected, which makes it too broad of a group to qualify as a "distinct and identifiable class." And for those reasons, we've determined that these are broader "matters" and not particular matters of general applicability."
So, it appears that I am OK to support the science discussion on-going on the PFAS test orders and the new ORD project to develop new high thru put data and computational models to support industrial chemicals.
Please let me know if you have any Qs.


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Washington, DC 20460

Citric Acid

Citric Acid is used as an inert ingredient and as a pesticide in residential, public access locations and hospitals. Citric Acid a known disinfectant, sanitizer (food contact and non-food contact), fungistat and herbicide. Citric Acid is on the 25B minimum risk pesticide list, therefore, there may be other types of pesticidal products that would not require registration.

Quats

The quats have a variety of uses pesticidal uses that include public health products and non-public health products. The quats have other non-pesticidal uses including but not limited to uses as a surfactant. Some of the quat compounds are cleared inert ingredients for use in pesticidal products.

According to the Final Work Plan (FWP) signed in 2017 the uses for ADBAC (a type of quat and the FWP includes several other quat compounds) include:

- Commercial, Industrial, Institutional, Premises and Equipment
    - Cadavers (not used to treat, mitigate, prevent or diagnose any diseases)
    - Hard non-porous surface sanitizer/disinfectant and cleaner
    - Non-porous surface sanitizer and cleaner
    - Commercial laundry uses
- Food Handling and Storage Establishment Premises and Equipment
    - Hard non-porous surface sanitizer/disinfectant and cleaner
    - Egg shell sanitization
    - Food and beverage processing plants (including dairies)
- Human Drinking Water
    - Ice Machines
    - Water holding tanks
    - Reverse osmosis units
- Medical/Dental/Veterinary Premises and Equipment
    - Hard non-porous sanitizer/disinfectant
    - Porous surface sanitizer
    - Laundry sanitizer
- Residential and Public Access Premises
    - Hard non-porous sanitizer/disinfectant
    - Porous surface sanitizer
    - Exterior surfaces
    - Laundry sanitizer
    - Humidifier waters
    - Antimicrobial paints
- Agricultural Uses
    - Hard non-porous surface sanitizer/disinfectant
    - Hoof trimming equipment
    - Shoe baths
    - Hatcheries and incubators (empty and occupied)
- Industrial Processes and Water Systems

    - Cooling water systems
    - Oil and gas drilling and fracking fluids
    - Paper mill processing water
    - Wastewater systems
- Materials Preservative
    - Paper products
- Aquatic Area Uses
    - Decorative fountains, pools and water features (as an algaecide and as mosquito control)
- Swimming Pools and Spas
    - Pool water treatment
    - Hard non-surface sanitizer and disinfectant
- Wood Preservation
    - Seasoned lumber as a termite control
    - Fresh lumber as sapstain control
    - Existing wood shingle and shake roofs/siding
- Other Uses
    - Residential lawns and turfs
    - Commercial and Golf turfs
    - Nursery ornamentals

Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Final Work Plan

Registration Review: Initial Docket Case Number 0350

March 2017

Approved by: _____ for _____ Date: 3/23/17

Yu-Ting Guilaran, P.E.
Director
Pesticide Re-evaluation Division

Approved by: _____ Date: 3/24/17

Steve Knizner
Director
Antimicrobials Division

Alkyl Dimethyl Benzyl Ammonium Chloride Registration Review Team

Human Health & Environmental Effects

Antimicrobials Division
Patricia Jennings
Diana Hsieh
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Environmental Fate and Effects Division
Mary Clock-Rust
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Elissa Reaves
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Risk Management
Rachel Ricciardi
Maria Piansay
Jose Gayoso
Jill Bloom
Eric Miederhoff

Office of General Counsel
Philip Ross

TERMS, ABBREVIATIONS AND SYMBOLS

AD	Antimicrobials Division
ADBAC	alkyl dimethyl benzyl ammonium chloride
A.I. or a.i.	active ingredient
aPAD	acute population adjusted dose
ASRI	activated sludge respiration inhibition
atm-m^3/mole	atmospheric pressure-cubic meter per mole
BCF	bioconcentration factor
°C	degrees Celsius
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CHO	Chinese hamster ovary
CMA	Chemical Manufacturers Association
CO_2	carbon dioxide
COC	concentration-of-concern
cPAD	chronic population adjusted dose
DCI	data call-in
DDAC	Didecyl Dimethyl Ammonium Chloride
EC_{50}	median (or 50 percent) effect concentration
EC_{05}	5 percent effect concentration
ECOTOX	ECOTOXicology
EDI	estimated daily intake
EDSP	Endocrine Disruptor Screening Program
E-FAST	Exposure and Fate Assessment Screening Tool
EPI Suite	Estimation Program Interface Suite
EPA	Environmental Protection Agency
FCN	food contact notification
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FWP	Final Work Plan
g/mol	grams per mole
GDCI	Generic DCI
GLN	guideline number
HEC	Human Equivalent Concentration
HPV	high production volume
IDS	Incident Data System
Koc	organic carbon normalized soil-water partition coefficient
Kd	soil-water partition coefficient
Kow	octanol-water partition coefficient
LC_{50}	median (or 50 percent) lethal concentration
LD_{50}	median (or 50 percent) lethal dose
LOAEC	lowest-observed-adverse-effect-concentration
LOEC	lowest-observed-effect-concentration
LOAEL	lowest-observed-adverse-effect-level
Log K_{ow}	logarithm of the octanol-water partition coefficient
µg	microgram
ml/g	milliliter per gram

mg/kg	milligram per kilogram
mg/kg/day	milligram per kilogram per day
mg/L	milligram per liter
mm Hg	millimeter of mercury
MOE	margin of exposure
MRID	Master Record Identification Number
MRL	maximum residue limit
N/A	not applicable
nm	nanometers
NOAEC	no-observed-adverse-effect-concentration
NOAEL	no-observed-adverse-effect-level
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organization for Economic Co-operation and Development
OPP	Office of Pesticide Programs
PAD	population adjusted dose
PAI	pure active ingredient
PDM	Probabilistic Dilution Model
%	percent
PC Code	Pesticide Chemical Code
PCF	pounds per cubic foot
pH	power of hydrogen or power of the concentration of the hydrogen ion
PHED	Pesticide Handler's Exposure Data
PIS	primary irritation score
pKa	power of the acid dissociation constant or negative base-10 logarithm of the acid dissociation constant of a solution
ppb	parts per billion
ppm	parts per million
PWP	Preliminary Work Plan
PWR	potable water rinse
QSAR	quantitative structure-activity relationship
RDDR	Regional Dose Deposition Ratio
RED	Reregistration Eligibility Decision
SAR	structure activity relationship
SF	safety factor
SSTS	Section Seven Tracking System
TEP	typical end-use product
TGAI	technical grade active ingredient
TMDL	total maximum daily loads
UF	uncertainty factor
UV/VIS	ultraviolet/visible light absorption
% w/w	percent weight per weight.
WP	wettable powder
WWTPs	wastewater treatment plants
USDA	United States Department of Agriculture

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1 Introduction

This document is the United States Environmental Protection Agency's (USEPA, EPA or "the Agency") Final Work Plan (FWP) for the Alkyl Dimethyl Benzyl Ammonium Chloride chemical case, herein referred to as ADBAC. The FWP document explains what EPA's Office of Pesticide Programs (OPP) knows about ADBAC, highlighting anticipated data and assessment needs, identifying the types of information that would be especially useful to the Agency in conducting the review, and providing a screening-level dietary risk assessment and an anticipated timeline for completing ADBAC's review.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders. The Agency intends, by sharing this information in the docket, to inform the public of what it knows about ADBAC and what types of new data or other information would be helpful for the Agency to receive as it moves toward a decision on ADBAC.

1.1 Statutory and Regulatory Authority

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States generally must be registered by the USEPA based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 CFR 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

1.2 Updates to the Workplan

Since the publication of the Preliminary Work Plan (PWP), the Agency has made the following updates:

- Updated Table 5 to reflect the current number of EPA registered products that contain ADBAC.

- Updated Section 1.7.1 to reflect the current number of human health incidents and to incorporate responses to the Weber (2016) article.
- Updated Section 2, "Anticipated Data Needs". In Table 14, a footnote was added to guideline numbers 850.3030, 850.3040, 875.2500, 860.1340, 860.1380, 860.1480, and Non-Guidelines: Tier I Honey bee larvae chronic oral toxicity, Tier I Honey bee adult chronic oral toxicity, and Tier II Semi-field testing for pollinators. Footnotes were deleted from Non-Guidelines: Tier I Honey bee adult acute oral toxicity, Tier I Honey bee larvae acute oral toxicity, Tier I Honey bee larvae chronic oral toxicity, Tier I Honey bee adult chronic oral toxicity, Tier II Semi-field testing for pollinators, and Tier III Field testing for pollinators. The timeframe was changed for guideline number 875.2500 and the test substance was changed for Non-Guideline: Tier II Semi-field testing for pollinators. In Table 15, study statuses were updated and additional footnotes were added.
- Deleted the "Guidance for Commenters" Section.
- Updated Section 7, "Next Steps".
- Updated spelling and grammatical errors.

No public comments were received on the initial docket. No changes were made to the registration review schedule of ADBAC. This document makes final the work plan for the ADBAC registration review process.

1.3 Case Overview

The docket for ADBAC (case #0350) has been established at http://www.regulations.gov in docket number EPA-HQ-OPP-2015-0737. Documents associated with this registration review can be viewed in this docket. Tables 1 and 2 below summarize the assessments and data needs relevant to this registration review case and the anticipated registration review schedule. Data required for reregistration are summarized in Table 15.

Table 1 – Anticipated Risk Assessments for Registration Review

Risk Assessment	Assessment Necessary to Support Registration Review	Date of Most Recent Assessment	Type of Assessment Required (New/Updated)	Data Anticipated as Needed (See Table 14 for details)
Dietary (food)	Yes	2006	Updated	Residue Data
Dietary (drinking water)	Yes	N/A	New	Activated Sludge Sorption Isotherm (ASSI) and Activated Sludge Respiration Inhibitor (ASRI)
Occupational Handler	Yes	2006	Updated	None
Residential Handler	Yes	2006	Updated	None
Occupational Post Application	Yes	2013	Updated	None
Residential Post Application	Yes	2006	Updated	Post Application Inhalation Exposure Turf Transferable Residue Dissipation

Risk Assessment	Assessment Necessary to Support Registration Review	Date of Most Recent Assessment	Type of Assessment Required (New/Updated)	Data Anticipated as Needed (See Table 14 for details)
Aggregate	Yes	N/A	Updated	None
Cumulative	No	N/A	None	None
Tolerance Review	Yes	2006	Updated	None
Ecological	Yes	2006[1]	Updated	Toxicity data for aquatic plants, benthic invertebrates, and honey bees

N/A = Not applicable

[1] For the Reregistration Eligibility Decision (RED), the antimicrobial uses assessed were once-through cooling towers and wood preservatives (antisapstain use) while the conventional uses assessed were applications to ornamental nurseries, turf, golf courses, mosquito larvicide and algaecide in puddles, ornamental ponds and pools.

Table 2 – Anticipated Registration Review Schedule

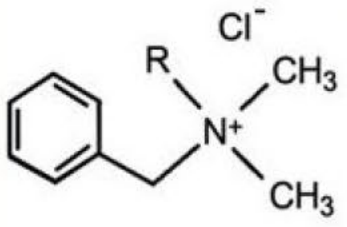
Anticipated Activity	Target Date*	Completion Date
Phase 1: Opening the Docket		
Open Docket and 60-Day Comment Period for Preliminary Work Plan	2016-09	2016-09
Close Public Comment Period	2016-11	2017-01
Phase 2: Case Development		
Issue Final Work Plan	2017-03	2017-03
Issue Data Call-In (DCI)	2018-03	
Receive Data to be Considered in Risk Assessment	2020-03	
Open 30-Day Public Comment Period for Preliminary Risk Assessment(s)	2021-09	
Close Public Comment Period	2021-10	
Phase 3: Registration Review Decision and Implementation		
Open 60-Day Public Comment Period for Proposed Decision	2022-03	
Close Public Comment Period	2022-05	
Issue Final Decision	2022-09	
Begin Post-Decision Follow-up	2022-09	
Total (years)	6	

*The anticipated schedule will be revised as necessary (*e.g.*, need arising under the Endocrine Disruptor Screening Program with respect to the active ingredients in this case).

1.4 Chemical Identification and Properties

Table 3 and 4 present the chemical and physical properties of the active ingredient to be assessed in case 0350: ADBAC. The ADBAC chemical case is composed of 19 compounds (PC Codes: 069104, 069105, 069106, 069107, 069119, 069137, 069140, 069141, 069175, 069184, 128928, 069171, 069154, 069111, 069125, 069122, 069167, 069195 and 129012). The Agency will use alkyl (40% C_{12}, 50% C_{14}, 10% C_{16}) dimethyl benzyl ammonium chloride (PC code 069105) as the model compound because this active ingredient has the highest number of active registrations and therefore, is expected to be the most representative compound for this case (EPA, 1994).

Table 3 – Chemical Identification of Representative ADBAC Active Ingredient

Chemical Name	ADBAC
Chemical Classification	Quaternary Amines
PC Code	069105
CAS Number	68424-85-1
Molecular Formula	$RC_9H_{13}NCl$ R= n-alkyl (C_{12} 40%, C_{14} 50%, C_{16} 10%)
Molecular Weight (grams/mole)	377.83
Molecular Structure	

The ADBAC product chemistry and physical property information relevant to risk assessment is summarized in Table 4, and details of the environmental fate information are discussed in Appendix B.

Table 4 – Physical-Chemical Properties for ADBAC (PC Code 069105)

Guideline No.	Parameter	Value	Source (MRID unless specified)
830.7000	pH	7.59	44467403
830.7050	UV/visible Absorption	None in 290-800 nm range	47398502
830.7300	Density (g/cm^3 at 25 °C)	0.9429	44467403
830.7370	Dissociation constant (pKa)	N/A	49740501
830.7550	Octanol-water partition coefficient at 25 °C (Log K_{ow})	3.91	EpiSuite v.4.11
830.7840	Solubility in water (mg/L)	10,000	EpiSuite v.4.11
None	Boiling Point (°C)	560.84	EpiSuite v.4.00
830.7950	Vapor pressure (mmHg) at 25 °C	$3.53x10^{-12}$	EpiSuite v.4.00
None	Henry's law constant at 25 °C ($atm\text{-}m^3/mol$)	$1.34x10^{-11}$	EpiSuite v.4.11

$atm\text{-}m^3/mol$ = atmosphere cubic meter per mole; °C = degrees Celsius; mg/L = milligrams per liter; mmHg = millimeters of mercury

1.5 Use/Usage Description

1.5.1 Registrations

There are 667 EPA-registered products that contain ADBAC as an active ingredient (a.i.), 664 of which are antimicrobial registered products and 3 that are conventional registered products. The 3 conventional registered products (EPA Registration Numbers 1021-2559, 9688-314 and 9688-317) are insecticides co-formulated with antimicrobial active ingredients and conventional insecticides. Additionally, of the 664 antimicrobial registered products, 24 products have conventional use sites. These 24 products include 14 technical products and 8 end use products. Seven of these end use products (EPA Registration Numbers 10324-94, 10324-99, 55364-5, 66784-1, 66784-2, 84115-1, and 87429-1) contain only antimicrobial ingredients and the conventional use sites include ornamental plants, ornamental trees, lawns and turf. The one other end use product (70385-3) contains insecticidal ingredients and is used on a wide variety of use sites to control insects and microorganisms.

Table 5 presents ADBAC chemical case's 19 structurally similar quaternary ammonium compounds (also known as QACs or quats) compounds, CAS numbers, ingredient names, and active registrations (at the time of ADBAC's FWP publication to the docket). The formulations include ready-to-use solutions, pressurized liquids, soluble concentrates, pellets/tablets, dust, aerosols, impregnated materials, and flowable concentrates. The product pesticide types include disinfectants, bacteriocides, bacteriostats, fungicides, fungistats, virucides, sanitizers, microbicides, microbiostats, algaecides, tuberculocides, antimicrobials, water purifiers, miticides, and slimicides. Several of ADBAC's products contain multiple active ingredients including but not limited to: other ADBAC chemical case compounds, Didecyl Dimethyl Ammonium Chloride (DDAC) chemical case compounds[1], glutaraldehyde, and pine oil. The three conventional registered products contain ADBAC chemical case compounds, DDAC chemical case compounds, plus any of the following active ingredients: cypermethrin, pyrethrins, and prallethrin.

[1] Documents pertaining to the registration review of the Didecyl Dimethyl Ammonium Chloride (DDAC) chemical case (case number 3003) can be accessed at http://www.regulations.gov in docket number EPA-HQ-OPP-2015-0740. The DDAC case, which includes active ingredients structurally similar to ADBAC active ingredients, is also being assessed through registration review.

Table 5 – Number of EPA Registered Products that contain ADBAC Sorted by PC Code

PC code	CAS Number	Ingredient Name	Number of Active Antimicrobial Product Registrations as of 3/14/17[1]	Number of Active Conventional Product Registrations as of 3/14/17[1]
069104	53516-76-0	Alkyl (60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}) dimethyl benzyl ammonium chloride	249	2
069105	68424-85-1	Alkyl (50%C_{14}, 40%C_{12}, 10%C_{16}) dimethyl benzyl ammonium chloride	309	1
069106	8001-54-5	Alkyl (50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}) dimethyl benzyl ammonium chloride	2	0
069107	139-08-2	Alkyl (100% C_{14}) dimethyl benzyl ammonium chloride	4	0
069111	8045-21-4	Alkyl (50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}) dimethyl ethylbenzyl ammonium chloride	10	0
069119	73049-75-9	Dialkyl (60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}) methyl benzyl ammonium chloride	33	0
069122	121-54-0	Benzenemethanaminium, N,N-dimethyl-N-(2-(2-(4-(1,1,3,3-tetramethylbutyl)phenoxy)ethoxy)ethyl)-, chloride	10	0
069125	1330-85-4	Dodecylbenzyl trimethyl ammonium chloride	1	0
069137	68424-85-1	Alkyl (60%C_{14}, 25%C_{12}, 15%C_{16}) dimethyl benzyl ammonium chloride	6	0
069140	61789-71-7	Alkyl (61% C_{12}, 23% C_{14}, 11% C_{16}, 2.5% C_{18}, 2.5% C_{10}, trace C_8) dimethyl benzyl ammonium chloride	1	0
069141	68424-85-1	Alkyl (58%C_{14}, 28%C_{16}, 14%C_{12}) dimethyl benzyl ammonium chloride	21	0
069154	85409-23-0	Alkyl (68%C_{12}, 32%C_{14}) dimethyl ethylbenzyl ammonium chloride	188	2
069167	68956-79-6	Alkyl (60%C_{14}, 30%C_{16}, 5%C_{12}, 5%C_{18}) dimethyl ethylbenzyl ammonium chloride	2	0
069171	68989-01-5	Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium saccharinate	7	0
069175	68391-01-5	Alkyl (67%C_{12}, 25%C_{14}, 7%C_{16}, 1%C_{18}) dimethyl benzyl ammonium chloride	29	0
069184	68424-85-1	Alkyl (95%C_{14}, 3%C_{12}, 2%C_{16}) dimethyl benzyl ammonium chloride	18	0
069195	68391-01-5	Alkyl (41%C_{14}, 28%C_{12}, 19%C_{18}, 12%C_{16}) dimethyl benzyl ammonium chloride	1	0
128928	63449-41-2	Alkyl (67%C_{12}, 25%C_{14}, 7%C_{16}, 1%C_8, C_{10}, and C_{18}) dimethyl benzyl ammonium chloride	6	0
129012	61789-18-2	Alkyl (as in fatty acids of coconut oil) trimethyl ammonium chloride	1	0

[1] Several of ADBAC's products contain multiple active ingredients. As a result, many products are recorded more than once under multiple ADBAC PC Codes.

The individual exposure scenarios in ADBAC assessments are developed by summing the total percent of ADBAC active ingredients on a product's label.

1.5.2 Summary of Registered Uses

Table 6 presents a summary of the registered uses of ADBAC that will be assessed in this registration review. This table also includes the application methods.

Table 6 – ADBAC Registered Uses that will be Assessed During Registration Review

Use	Application Method	ADBAC Concentration Range/ Application Rate[1]
Agricultural Premises and Equipment		
Hard Surface Sanitizer/Disinfectant	Spray, Mop, Sponge, Wipe	200 to 16,000 ppm[2]
Hoof Trimming Equipment	Dip	625 to 2,800 ppm
Entryway Shoe Baths	Shoe Bath	350 to 2,000 ppm
Hatchery Rooms – Empty	Fog	1.1 to 3.8 %
Incubators and Hatchers - Occupied	Fog	919 ppm
Aquatic Areas		
Decorative fountains, pools and water displays (Algaecidal use)	Open pour	2 ppm
Commercial, Industrial, Institutional, Premises and Equipment		
Cadavers – Cleansing of Exterior Body Surfaces	Sponge, Towel, Brush	188 to 528 ppm
Hard Surface Sanitizer/Disinfectant	Spray, Mop, Sponge	100 to 16,000 ppm[2]
Commercial Laundry	Open pour	780 ppm
Drywall, trim and frame lumber	Spray	450 to 1,700 ppm
Garbage trucks and equipment	Spray	450 to 1,700 ppm
Painted Surfaces (Antimicrobial Paint)	Brush, Roller	5,200 ppm[3]
Soft Surface Deodorizer (Carpets)	Spray, Mop	450 to 1,700 ppm
Food Handling/Storage Establishments Premises and Equipment		
Hard Surface Sanitizer/Disinfectant	Spray, Mop, Sponge	200 to 16,000 ppm[2]
Egg Shell Sanitation	Spray	200 to 470 ppm
Dairies, beverage and food processing plants	Fog	0.34%
Human Drinking Water (Sanitization of Interior Hard Surfaces of Equipment and Tanks)		
Ice Machines, Water holding tanks, Reverse Osmosis (RO) units	Open Pour, Spray, Circulate in Place (CIP)	400 to 470 ppm
Industrial Processes and Water Systems		
Cooling Water Systems	Open pour	2 to 20 ppm
Oil and gas drilling and fracturing fluids	Open pour	2 to 500 ppm
Paper Mill Processing Water (Whitewater)	Open pour	0.5 to 100 ppm
Wastewater Systems	Open pour	50 to 250 ppm
Material Preservative		
Paper Products	Open Pour	600 ppm
Medical/Dental/Veterinary Premises and Equipment		
Hard Surface Sanitizer/Disinfectant	Spray, Mop, Sponge, Wipe	200 to 16,000 ppm[2]
Painted Surfaces (Antimicrobial Paint)	Brush, Roller	5,200 ppm[3]
Salon/Barber instruments and tools	Immersion	200 to 1,100 ppm

Use	Application Method	ADBAC Concentration Range/ Application Rate[1]
Residential and Public Access Premises		
Hard Surface Sanitizer/Disinfectant	Spray, Mop, Sponge, Wipe	200 to 16,000 ppm[2]
Humidifier Water (Evaporative Humidifiers Only)	Open Pour	7 to 510 ppm
Exterior Surfaces (decks, walkways and patios)	Spray	740 to 17,000 ppm
Painted Surfaces (Antimicrobial Paint)	Brush, Roller	5,200 ppm[3]
Waterbed Water	Open Pour	35 to 164 ppm
Swimming Pools and Spas		
Hard Surface Sanitizer/Disinfectant	Spray, Mop, Sponge, Wipe	200 to 16,000 ppm[2]
Pool and Spa Water Treatment	Open Pour Liquid or Place Solid	2 to 8 ppm
Wood Preservation		
Seasoned lumber (termite control)	Pressure Treat/Double Vacuum	0.1 to 0.6 pcf
Fresh cut lumber (sapstain control)	Dip or Spray	1.9 to 3.0%
Existing wood shingle and shake roofs and siding	Brush or Spray	0.5 to 3.0%
Conventional Uses		
Residential lawns and turf	Spray treatment	6.8 lbs a.i./Acre[4]
Commercial turf	Spray treatment (10 acre max)	0.75 lbs a.i./Acre[5]
Golf course, greens and tees	Spray treatment (10 acre max)	0.8 lbs a.i./Acre[5]
Nursery ornamentals	Spray or drench treatment	0.25 lbs a.i./plant
Decorative fountains, pools and water displays (mosquito control)	Open pour	350 ppm a.i.

[1] The concentration ranges/application rates are based on the ADBAC content of the end use products. These rates do not include DDAC.
[2] The rate of 16,000 ppm is for products such as 74436-1 and 80346-1, which are two-part formulations. Part A contains 32,000 ppm ADBAC and is mixed in equal amounts with Part B, which contains hydrogen peroxide, to yield a solution containing 16,000 ppm ADBAC. The rate for all other labels is 200 to 5000 ppm.
[3] Only one product (64695-1) has this use.
[4] Limited to 6 spot treatments per year with a retreatment interval of 10 days.
[5] Limited to 6 treatments per year with a retreatment interval of 10 days, not to exceed 10 acres per treatment.

Some registered uses of ADBAC will be removed from EPA product labels in accordance with the Reregistration Eligibility Decision (RED)[2]. Labeling changes were specified as part of the risk mitigation measures outlined in the August 2006 ADBAC RED. "Table 13. The Labeling Changes Summary Table" in the ADBAC RED describes how language on labels containing ADBAC active ingredients should be amended. The registered use in Table 7 was not supported at the time of the RED and therefore, is one example of an ADBAC use that will be removed from EPA product labels through ADBAC's post-RED label review process.

[2] The ADBAC RED is located at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0339.

Table 7 – ADBAC Registered Use that will be Removed from EPA Product Labels

Use	Application Method	Concentration Range/ Application Rate
Dairy Cows – Udder, flanks and teats[1]	Wash with Towel	72 to 100 ppm ai

[1] This use is included on two product labels (9768-12 and 1839-189). This use will be removed from EPA Reg. No. 9768-12 because it is not an EPA pesticidal use. Stepan Company has requested the voluntary cancellation of EPA Reg. No. 1839-189 in response to the ADBAC Product Specific Data Call-In. This use is only one example of ADBAC uses that will be removed from the EPA product labels through ADBAC's post-RED label review process.

All registrants making claims that their products control mosquitoes, including products containing ADBAC, are required to submit efficacy data to the Agency. According to 40 CFR 158.2160, efficacy data are required to be submitted to the Agency if a pesticide product bears a claim to control public health pests, including mosquitoes, that may directly or indirectly transmit diseases to humans. Therefore, the Agency reserves the right to require submission of efficacy data for all products containing ADBAC active ingredients with mosquito control claims.

1.5.3 Usage Information

Production volume data for the years 2011 through 2014 indicate that no more than 90 million kilograms (approximately 198 million pounds) of ADBAC are sold per year in the United States. Data for the years 2015 and 2016 were not used in this estimate since data collection is still in progress.

1.6 Regulatory History

In 1947, the first pesticide product containing an ADBAC active ingredient was registered in the United States. The oldest currently-registered product containing an ADBAC a.i. was registered in 1956 under PC Code 069105. These pesticides were classified as List A chemicals for which a registration standard was issued by EPA in 1985. When the list of active ingredients undergoing reregistration was published in 1989, 43 additional active ingredients were added to the reregistration case.

In 1988, the Agency issued PR Notice 88-2 outlining "Clustering of Quaternary Ammonium Compounds," in which structurally similar quats were clustered into 4 groups as follows:

Group I: The alkyl or hydroxyalkyl (straight chain) substituted Quats

Group II: The non-halogenated benzyl substituted Quats (including hydroxybenzyl, ethylbenzyl, hydroxyethylbenzyl, naphthylmethyl, dodecylbenzyl, and alkyl benzyl)

Group III: The di- and tri-chlorobenzyl substituted Quats

Group IV: Quats with unusual substitutes (charged heterocyclic compounds).

ADBAC's chemical case was clustered into Group II and the Agency completed a Reregistration Eligibility Decision (RED) for ADBAC in August 2006. The post-RED Generic Data Call-Ins (DCIs) were issued in December 2014 and the post-RED Product Specific DCIs were issued in February and March 2015[3]. The RED specified label changes to mitigate human health and environmental risks and the Agency acknowledges that there are existing labels not yet in compliance with these risk mitigation measures. Some of these mitigation measures will impact the forthcoming risk assessments for the ADBAC registration review, and the Agency is actively working to bring these labels into compliance prior to the development of the registration review risk assessments.

A consortium was formed by ADBAC registrants to support the reregistration activities of the ADBAC chemical case. The consortium, the ADBAC Issues Steering Committee/Joint Venture, is comprised of the following registrants: Lonza Incorporated, Mason Chemical Company, and Stepan Company.

Since reregistration, several human health risk assessments have been completed to support new uses and label amendments. The most recent human health risk assessment for ADBAC was completed on December 19, 2013 (D413897) to assess inhalation exposures for a proposed product to be applied by fogging. The Agency's most recent ecological risk assessment for ADBAC was completed on August 2, 2006 (prepared for the RED).

1.6.1 Tolerance Information

EPA has established tolerance exemptions for indirect food uses (food-contact surfaces) for residues of some ADBAC active ingredients. The end-use concentration of all quaternary chemicals in solution is not to exceed 200 or 400 ppm of active quaternary compound. These exemptions are listed in Table 8 and are located in 40 CFR part 180.940.

Table 8 – Tolerance Exemptions under 40 CFR Part 180.940

Chemical Name	CAS No.	PC Code	Tolerance Exemption
Quaternary ammonium compounds, alkyl (C_{12}-C_{18}) benzyldimethyl, chlorides	8001-54-5	069106	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.
Quaternary ammonium compounds: n-alkyl (C_{12-18}) dimethyl benzyl ammonium chloride	68424-85-1	069105 069137 069141 069184	When ready for use, the end-use concentration of all quaternary chemicals in solution is not to exceed 400 ppm of active quaternary compound.
Quaternary Ammonium Compounds: n-alkyl (C_{12-14}) dimethyl ethylbenzyl ammonium chloride, average	85409-23-0	069154	When ready for use, the end-use concentration of all quaternary chemicals in solution is not

[3] ADBAC's post-RED Generic Data Call-Ins (GDCIs) and Product Specific Data Call-Ins (PDCIs) are located at http://www.regulations.gov in docket number EPA-HQ-OPP-2006-0339.

Chemical Name	CAS No.	PC Code	Tolerance Exemption
molecular weight (in amu), 377 to 384			to exceed 400 ppm of active quaternary compound.
Quaternary ammonium compounds n-alkyl (C_{12}-C_{18}) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu) 384	8045-21-4 68956-79-6	069111 069167	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound.

The Agency notes that not all ADBAC active ingredients have established tolerances or tolerance exemptions for residues in/on food, and will evaluate the need for revisions to the existing tolerance exemptions during registration review. Table 9 lists the ADBAC active ingredients used in food contact products without a tolerance or tolerance exemption.

Table 9 – ADBAC Active Ingredients with Food Contact Product Labels without a Tolerance or Tolerance Exemption

Chemical Name	CAS No.	PC Code
Alkyl (60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}) dimethyl benzyl ammonium chloride	53516-76-0	069104
Alkyl (50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}) dimethyl ethylbenzyl ammonium chloride	8045-21-4	069111
Dialkyl (60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}) methyl benzyl ammonium chloride	73049-75-9	069119
Benzenemethanaminium, N,N-dimethyl-N-(2-(2-(4-(1,1,3,3-tetramethylbutyl) phenoxy)ethoxy)ethyl)-, chloride	121-54-0	069122
Alkyl (60%C_{14}, 30%C_{16}, 5%C_{12}, 5%C_{18}) dimethyl ethylbenzyl ammonium chloride	68956-79-6	069167
Alkyl (67%C_{12}, 25%C_{14}, 7%C_{16}, 1%C_{18}) dimethyl benzyl ammonium chloride	68391-01-5	069175
Alkyl (67%C_{12}, 25%C_{14}, 7%C_{16}, 1%C_{8}, C_{10}, and C_{18}) dimethyl benzyl ammonium chloride	63449-41-2	128928

The following ADBAC PC Codes do not include food contact product labels and therefore do not require a tolerance or tolerance exemption: 069107, 069125, 069140, 069171, 069195 and 129012.

ADBAC has been listed as a food contact substance by the FDA under FFDCA Section 409. There is a food contact notification[4] (FCN) for ADBAC. FCNs are only effective for the manufacturer or supplier identified in the notification (see Table 10).

[4] More information about food contact notifications (FCNs) can be found at http://www.accessdata.fda.gov/scripts/fdcc/?set=fcn and http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=iaListing&page=30.

Table 10 – Summary of ADBAC Food Contact Notifications

FCN No.	Food Contact Substance	Manufacturer	Effective Date	Intended Use & Limitations/Specifications
460	Benzenemethanaminium, N,N-dimethyl-N-(2-(2-(4-(1,1,3,3,-tetramethylbutyl) phenoxy) ethoxy)-ethyl)-,chloride (CAS Reg. No. 121-54-0) also known as Benzethonium Chloride USP	Lonza, Inc.	Dec 7, 2004	As an antimicrobial agent in no-rinse hand sanitizers for food handlers. Benzethonium Chloride USP may be used at levels not to exceed 0.2 percent by weight of the finished hand sanitizer formulations.

ADBAC has also been listed as an indirect food additive under 21 CFR part 176 and 175, and as a direct food additive under 21 CFR part 172 (see Tables 11 and 12).

Table 11 – Summary of ADBAC Indirect Food Additives

CFR Section	Use	Maximum Residue Level
176.300	Slimicides used as antimicrobial agents in the manufacture of paper or paperboard that may contact food	None given
175.300	Resinous and polymeric coatings	None given
175.105	Substances for use as components of adhesives	None given

Table 12 – Summary of ADBAC Direct Food Additives

CFR Section	Use	Maximum Residue Level
172.165	Food Additives for direct addition to food for human consumption in sugar cane juice	The additive is applied to the juice in the following quantities: • n-dodecyl dimethyl benzyl (00.25-1.0 ppm) • n-dodecyl dimethyl ethylbenzyl ammonium chloride (3.4-13.5 ppm) • n-hexadecyl dimethyl benzyl ammonium chloride (1.5-6.0 ppm) • n-octadecyl dimethyl benzyl ammonium chloride (0.25-1.0 ppm) • n-tetradecyl dimethyl ammonium chloride (3.0-12.0 ppm) • n-tetradecyl dimethyl ethylbenzyl ammonium chloride (1.6-6.5)

1.7 Incidents

1.7.1 Human Health

Incidents Reported in the OPP Incident Data System

Since the 2006 RED, 2237 individual human health incidents have been reported for ADBAC in OPP's Incident Data System (IDS) for the time period spanning from September 1, 2006 to March 3, 2017. Of these 2237 incidents, 8 involved products could not be identified and 53 involved products have since been cancelled. A summary of the remaining 2176 incidents is given in Table 13. The largest number of incidents (814) occurred when handling liquid concentrate products, followed by ready to use (RTU) spray products (337), RTU trigger sprayer products (244), and RTU wipes (235). The liquid concentrate products are used to prepare dilute working solutions that can be applied by a variety of methods including spray, mop, wipe or fog.

To determine if the incident was caused by handling of the liquid concentrate during preparation of the working solution or if the incident was caused by the application of the working solution, it would be necessary to review each of the 814 liquid concentrate incidents.

In terms of severity, most of the incidents (2043) were rated as HC (human moderate), followed by 85 rated as HB (human major), 33 rated as HD (human minor), seven rated as HA (human fatality) and eight rated as HE (severity unknown). The circumstances leading to the seven HA incidents are listed below:

- A maintenance worker at a gas station used an ADBAC/DDAC disinfectant product. Another worker there was allegedly exposed to it and developed respiratory distress and ultimately died. She had previously had chronic obstructive pulmonary disease.
- An individual ingested an ADBAC/DDAC powder product along with another non-pesticidal cleaning product in a correctional facility.
- An airline employee developed respiratory distress resulting in death. Chemical exposure to an ADBAC/DDAC product and other three cleaning products was the potential cause. No other details were provided.
- A two-year-old asthmatic child who used a breathing machine died after removing an ADBAC RTU household cleaning and disinfectant product from an unlocked cabinet and spilling it on toys.
- A 34-year-old diabetic resident of a nursing home had a heart attack and later died at the hospital. A partially used can of ADBAC foam product was found in her room. The director of nursing indicated that this patient had previously used this product to clean her room without incident.
- A person deliberately inhaled an ADBAC foaming disinfectant product.
- A 68-year dementia patient in a nursing home ingested an ABDAC/DDAC disinfectant product that was being used to clean wheelchairs during the overnight shift.

Table 13 – Summary of ADBAC Human Health Incidents Since the RED (August 2006)

Type of Product (RTU = Ready to Use)	Number of Incidents					
	Human Fatality	Human Major	Human Moderate	Human Minor	Severity Unknown	Total
Liquid Concentrate	3	31	751	27	2	814
Powder or Solid	1	0	10	0	0	11
RTU Aerosol Can	1	3	52	0	0	56
RTU Foam	1	5	141	2	0	149
RTU Insecticide	0	1	9	0	0	10
RTU Solution for Pool Treatment	0	4	152	0	1	157
RTU Solution	0	5	70	0	1	76
RTU Spray	0	14	323	0	0	337
RTU Toilet Bowl Disinfectant	0	3	74	0	0	77
RTU Trigger Sprayer	1	16	224	1	2	244
RTU Wipe	0	3	227	3	2	235
Tablet	0	0	10	0	0	10
Total of Above	7	85	2043	33	8	2176

In addition to the incidents reported in individual reports discussed above, 16,559 incidents were reported in quarterly aggregate incident summaries. In terms of severity, most of the aggregate incidents (16,411) were rated as HD and the remainder (148) were rated as HE. The Agency will assess human health incidents in ADBAC's registration review risk assessment.

Epidemiology Studies and Incidents Reported in the Literature

There are reports in the literature of work-related asthma associated with exposure to cleaning agents and disinfectants, and some of these reports relate to the use of the quaternary ammonium compounds (QACs). The earliest reports include a case of a laundry worker who developed asthma after using a disinfectant containing QACs (Innocenti, 1978), a pharmacist who had asthma attacks when contacting a floor cleaning solution containing QACs (Burge, 1994), and a worker who had occupational asthma caused by prolonged exposure to cleaning agents containing QACs (Berstein, 1994). Three more cases were reported in Purohit (2000) of nurses who experienced asthma symptoms when preparing a 10% solution of disinfectant containing QAC, cleaning surgical instruments in a tray with a QAC disinfectant, and entering a room where a solution of disinfectant containing 40% QAC was kept. In a multistate report of 401 cases of pesticide related illness of health care workers (Mehler et al, 2010), QACs were involved in the most cases (151) followed by glutaraldehyde (101) and sodium hypochlorite (71). In terms of occupation, janitors and housekeepers had the most cases (95), followed by nursing/medical assistants (64) and health technicians (59).

In Gonzalez (2013), the association between disinfection with QACs and asthma in health care workers was investigated. This investigation was conducted in a cohort of 543 workers, which consisted of registered nurses (37.1%), auxiliary nurses (16.4%), cleaners (17.3%) and administrative staff (32.8%). Of the 543 workers, 335 were exposed to QACs as part of their normal workday. Registered and auxiliary nurses and cleaners reported a significantly higher risk of reported physician diagnosed asthma and nasal symptoms than administrative staff. This risk was particularly marked during disinfection tasks and when exposed to QACs. Exposure to QACs significantly increased the risk of reported physician diagnosed asthma with an adjusted odds ratio of 7.56 (95% CI = 1.84 – 31.05) compared to an adjusted odds ratio of 1.0 for persons not exposed. Exposure to QACs also increased the incidences of nasal symptoms at work with an odds ratio of 3.21 (95% CI = 1.42-7.22). No significant association was found with other exposures such as latex gloves, chlorinated products/bleach or glutaraldehyde. The highest risk was associated with tasks involving dilution of disinfection products by manual mixing. An editorial on this study (Heedrick, 2014) concluded that "Initiatives are needed in particular to improve education and labeling of products and to reduce exposure to disinfectants and cleaning agents."

In response to the increasing evidence that chemicals used for environmental surface cleaning in health care can cause respiratory illnesses such as asthma, the Cleaning and Disinfecting in Health Care (CDHC) Working Group was established to provide a more integrated approach to effective environmental surface cleaning and disinfection while protecting the respiratory health of health care personnel. This working group is part of the National Institutes of Safety and Health (NIOSH) National Occupational Research Agenda (NORA) and includes experts in inhalation toxicology, industrial hygiene, epidemiology, and infection control. This group recently published an article (Quinn, 2015) that discusses the potential hazards of the chemicals

used for cleaning and disinfection, including quats, and how those hazards could be reduced by a better understanding of the efficacy of cleaning and disinfecting products and procedures. In particular, improved guidance is needed to assist health care institutions in determining if cleaning is sufficient for non-clinical public spaces and floors. Such guidance could be used to reduce the amount of disinfectant used and associated worker exposures. The article also notes that asthma symptoms or exacerbations have been associated with the use of sprays.

In contrast to the CDHC Working Group, Weber (2016) concludes that dermatitis and respiratory symptoms (e.g., asthma) as a result of chemical exposures, including low-level disinfectants (which include ADBAC), are exceedingly rare. The authors examined the medical records for an occupational health clinic that serves the employees of the University of North (UNC) Carolina Hospital. This clinic is staffed by 2 part-time physicians, 1 full-time family nurse practitioner, and 2 full-time nurses. Over the time period studied, 2003-2012, UNC Hospital employed 69,075 full-time work years, which constituted 144 million person days of exposure. Injuries or illnesses caused by chemical exposures were uncommon. Overall, 70 of 128 chemical exposures were caused by a known germicide (i.e., antiseptic, high-level disinfectant, or low-level disinfectant), including alcohol 17, quaternary ammonium compound 18, germicide (not specified) 12, glutaraldehyde 7, peracetic acid 6, hypochlorite (bleach) 5, phenol 3, and chlorhexidine 2. Other chemicals included floor strippers, cleaning agents, formaldehyde, xylene, toilet disinfectants, and miscellaneous. The authors acknowledge that unprotected exposures to high-level disinfectants may cause dermatitis and respiratory symptoms and they recommend the use of engineering controls (e.g., closed containers, adequate ventilation) and personal protective equipment (e.g., gloves) to minimize exposure to high-level disinfectants. As noted above, ADBAC is considered to be a low level disinfectant and therefore is not included in this author's recommendation for engineering controls.

In response to the Weber (2016) article, a letter was written by Pechter and Rosenman (2016) to the editor of the publishing journal. This letter states that the conclusion of Weber (2016) is not supported by the occupational health clinic data or the literature review. Over 40 articles have documented the association of cleaning products, and specifically disinfectants used in hospitals, with asthma. Workers in cleaning occupations do not frequently report their work-related illnesses because of discouragement by employers, job insecurity and marginalization of the occupational category. The letter concludes that: "failing to recognize the hazards of disinfectants along with the blanket advice to continue to disinfect environmental surfaces leads to overuse and overexposure of hospital staff to these antimicrobial pesticides".

In response to Pechter and Rosenman (2016), Weber (2017) disagreed with many of the issues and criticisms raised. Weber's response discusses the substantial morbidity and mortally associated with healthcare-associated infections (HAIs) and how daily disinfection can reduce HAIs. Weber notes that disinfectant use is only recommended for the decontamination of environmental surfaces in contact with patients and is not recommended for non-patient areas such as offices. Weber also states that most of the literature is focused on the risks of asthma from high-level disinfectant uses and that there are fewer studies on low-level disinfectant uses. In addition, Weber states that the 40 articles mentioned in the letter were not based on clinical trials or prospective cohort studies. Weber does agree with Pechter and Rosenman that additional research is needed and suggests that prospective studies with appropriate clinical tests (i.e.

pulmonary function tests and human challenge studies) are needed to document possible allergies to low-level disinfectants and disinfectant-precipitated asthma. Weber also agrees that training and PPE should be provided to minimize exposures.

The EPA plans to consider all available epidemiological information in the ADBAC registration review risk assessment.

1.6.2 Ecological

There are no ecological incidents reported in the Incident Data System (IDS) as of June 6, 2016. No reports of incidents with wildlife were found in a search of the Ecological Incident Information System (EIIS) conducted June 9, 2016.

2 Anticipated Data Needs

The studies listed in Table 14 are expected to be needed for the registration review of ADBAC. Data requirements outstanding from the August 2006 ADBAC Reregistration Eligibility Decision (RED) are outlined in Table 15. The Agency anticipates reviewing any data received in response to the post-RED DCIs as well as data required for this registration review prior to conducting the registration review risk assessments for ADBAC.

Table 14 – Antimicrobial and Conventional Studies Anticipated as Needed for the Registration Review of ADBAC

Guideline Number (GLN)	Study Name	Test Substance	Time Frame (Measured in months from DCI Receipt)	Risk Assessment(s) Data Will Support	Use Site(s) Triggering Anticipated Data Requirement	Applicable Exposure Scenario
835.1110[1,2]	Activated Sludge Sorption Isotherm (ASSI)	TGAI	12	Ecological and Drinking Water	Antimicrobial uses: Recirculating cooling towers, air washer systems, wood preservatives, and swimming pools	Ecological
850.3300[3,4,5]	Activated Sludge Respiration Inhibition (ASRI)	EUP, PAI, TGAI	12	Ecological and Drinking Water		Ecological
835.4100	Aerobic soil metabolism	TGAI or PAIRA	24	Ecological	Conventional uses	Ecological
Non-Guideline[6,7,8,9]	Whole sediment: chronic freshwater invertebrates (with an amphipod, for example, *Hyalella azteca*)	TGAI	24	Ecological	Antimicrobial and conventional uses	Ecological
Non-Guideline[7,8,10]	Whole sediment: chronic marine/estuarine invertebrates (with an amphipod, for example, *Leptocheirus plumulosus*)	TGAI	24	Ecological	Antimicrobial and conventional uses	Ecological
850.2100[11,12]	Avian Acute oral (with a passerine species)	TGAI	12	Ecological	Conventional uses	Ecological
850.2300[12]	Avian Reproduction	TGAI	24	Ecological	Conventional uses	Ecological
850.4100 and 850.4225[13,14]	Tiers I and II Terrestrial plant toxicity-Seedling emergence	TEP	12	Ecological	Conventional uses	Ecological
850.4150 and 850.4250[14,15]	Tiers I and II Terrestrial plant toxicity-Vegetative vigor	EUP, TGAI	12	Ecological	Conventional uses	Ecological
Non-Guideline[12,16]	Tier I Honey bee adult acute oral toxicity	TGAI	12	Ecological	Conventional uses	Ecological

Guideline Number (GLN)	Study Name	Test Substance	Time Frame (Measured in months from DCI Receipt)	Risk Assessment(s) Data Will Support	Use Site(s) Triggering Anticipated Data Requirement	Applicable Exposure Scenario
Non-Guideline[12,17]	Tier I Honey bee larvae acute oral toxicity	TGAI	12	Ecological	Conventional uses	Ecological
Non-Guideline[8,12, 18]	Tier I Honey bee larvae chronic oral toxicity	TGAI	12	Ecological	Conventional uses	Ecological
Non-Guideline[8,12,19]	Tier I Honey bee adult chronic oral toxicity	TGAI	12	Ecological	Conventional uses	Ecological
850.3030[8,12,20]	Tier I Honey bee toxicity of residues on foliage	TEP	12	Ecological	Conventional uses	Ecological
Non-Guideline[8,12,21,22,23]	Tier II Semi-field testing for pollinators	TGAI	24	Ecological	Conventional uses	Ecological
850.3040[8,12,24,25,26]	Tier III Field testing for pollinators	TGAI	24	Ecological	Conventional uses	Ecological
860.1340[8]	Residue analytical method for data collection	ROC	24	Dietary exposure assessment for egg wash	Antimicrobial use: Egg Wash	Eggs
860.1380[8]	Storage stability	TEP or ROC	24	Dietary exposure assessment for egg wash	Antimicrobial use: Egg Wash	Eggs
860.1480[8]	Meat, Milk, Poultry, Eggs	TGAI	24	Dietary exposure assessment for egg wash	Antimicrobial use: Egg Wash	Eggs
875.2100[27]	Turf Transferable Residue Dissipation	TEP	12	Residential Post-application	Conventional use: Turf	Dermal and Incidental Oral
875.2500[8,28]	Inhalation Exposure – Post Application	TEP	24	Residential Post-application	Humidifier Water	Inhalation

TGAI = Technical Grade Active Ingredient; EUP = End-Use Product; PAI = Pure Active Ingredient; Pure Active Ingredient, Radiolabeled; TEP = Typical End-Use Product; ROC = Residue of Concern

Footnotes
[1] If the ASSI study does not demonstrate a strong potential to sorb during activated sludge treatment, the Agency may require verification of results from the ready biodegradability study (MRID 46865601) or an appropriate wastewater treatment plant (WWTP) biodegradability study as determined by the results of the ASRI test.
[2] EPA has published a final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003.
[3] EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: https://www regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021.
[4] OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en.

[5] The results of the ASRI, GLN 850.3300, will determine which of the four biodegradation tests would be expected to be required.
◦If the ASRI test EC_{50} is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 would be expected to be required. If the ASRI test EC_{50} is greater than 20 mg/L, then the Agency would expect to require the registrant to conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge, or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot Test.
◦If the Ready Biodegradability study is conducted and passes, then no further testing would be expected to be required. If, however, the antimicrobial fails the Ready Biodegradability study, then the (i) Biodegradation in Activated Sludge, or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot study would be expected to be required.
[6] The anticipated DCI will require conduct of the study according to ORD Study Method EPA 600/R-099-064 but with 12 replicates per treatment (4 for 28-d survival and growth and 8 for the remainder of the test) with 10 neonates per replicate.
[7] The guidance for the formulated sediment study can be found in OECD 218 Sediment-Water Chironomid Toxicity Test using Spiked Sediment.
[8] The anticipated DCI will require that a protocol be approved by the Agency prior to the initiation of the study.
[9] The guideline is partially fulfilled. Testing on one additional freshwater species is needed.
[10] The anticipated DCI will require conduct of the study according to ORD Study Method: EPA 600/R-099-020 but with 10 replicates per treatment with 20 neonates per replicate.
[11] OECD TG 233 using the "LD50- slope test" or "limit dose test" can be used instead of OCSPP 850.2100 for certain species and conditions (e.g., causes no delayed effects, causes no regurgitation). Details on the species and conditions under which TG 233 would not fulfill the data requirement are described at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-classifying-studies-conducted-using-oecd.
[12] The study must be conducted on all conventional uses, including mosquito uses.
[13] In a Federal Register Notice dated June 27, 2012, test guidelines 850.4100 and 850.4225 were merged and harmonized into OCSPP 850.4100. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028.
[14] Guideline studies are required to assess the impact on nontarget plants resulting from runoff and drift of the end-use products. The anticipated data are intended to provide an understanding of the relative sensitivity of a wide-range of terrestrial plants and are not intended to be specific to the actual target crop. Data are required for six species of dicots from at least four families, one species of which is soybean (*Glycine max*). Data are required for four species of monocots from at least two families, one species which is corn (*Zea mays*). At least one of either the monocot or dicot species must be a root crop.
[15] In a Federal Register Notice dated June 27, 2012, test guidelines 850.4150 and 850.4250 were merged and harmonized into OCSPP 850.4150. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028.
[16] See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en.
[17] OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (*Apis mellifera*) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en.
[18] OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD draft guidance has is being developed, see OECD 2013b. OECD Draft Guidance Document Honey Bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure. http://www.oecd.org/env/ehs/testing/Draft_GD_honeybees_rep_exp_for_2nd_CR_25_November_2013.pdf.
[19] OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus spp.* and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295.
[20] USEPA. 2012b. "Honey Bee Toxicity of Residues on Foliage." Ecological Effects Test Guidelines OCSPP 850.3030. EPA 712-C-018. Data are required when the product formulation contains one or more active ingredient(s) having an acute LD50 of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.
[21] The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based upon lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
[22] Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of either a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (*Apis mellifera L.*) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.

[23] For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613 – 616.
[24] The need for a field test for pollinators will be determined based upon lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
[25] See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11 – 14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. http://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.
[26] USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
[27] In conjunction with the 2007 40 CFR Part 158 Data Requirements, HED typically requires submission of a turf transferable residue (TTR) study in order to determine exposure and risk associated with contacting treated turf. The estimated residential turf post-application exposure using default TTR values for ADBAC is not minimal in comparison to the level of concern. The calculated MOE from the 2006 RED is not greater than 10 times higher than the level of concern, with the lowest MOE = 97 compared to the LOC of 100. Future refinements of this post-application exposure for ADBAC are anticipated in order to incorporate new TTR data and to incorporate any advances in EPA risk assessment methodology. Therefore, EPA is requiring the 40 CFR TTR data to facilitate any necessary exposure assessment refinements and to further EPA's general understanding of the availability of turf transferable pesticide residues.
[28] A post application inhalation exposure study for humidifier water (MRID 47222901) was submitted after the RED, however, the LOQ of 0.026 mg/m^3 is not low enough to permit comparison to the HEC of 0.018 mg/m^3 which has a target MOE of 100. A new study needs to be conducted with an LOQ of 0.00018 mg/m^3 to allow for this comparison. In addition, the application rate of 100 ppm used in the study is less than the maximum application rate of 510 ppm allowed by the labels.

Table 15 – Antimicrobial Data Required through the December 2014 post-RED Generic Data Call-Ins (GDCIs) for ADBAC

GLN	Study Name	Test Substance	Time Frame (Measured in months from DCI Receipt)	Risk Assessment(s) Data Will Support	Use Site(s) Triggering Anticipated Data Requirement	Applicable Exposure Scenario	Status[18]
875.1100[1,2]	Dermal Exposure - Outdoor	TEP	24	Occupational and Residential Handler	See Footnote 1	See Footnote 1	Partially Satisfied[3,4]
875.1200[1,2]	Dermal Exposure - Indoor	TEP	12	Occupational and Residential Handler	See Footnote 1	See Footnote 1	Partially Satisfied[3,4]
875.1300[1,2]	Inhalation Exposure - Outdoor	TEP	24	Occupational and Residential Handler	See Footnote 1	See Footnote 1	Partially Satisfied[3,4]
875.1400[1,2]	Inhalation Exposure - Indoor	TEP	24	Occupational and Residential Handler	See Footnote 1	See Footnote 1	Partially Satisfied[3,4,5]
875.2300[6]	Indoor Surface Residue Dissipation	TEP	12	Residential Post Application	See Footnote 6	See Footnote 6	Partially Satisfied[7]
875.2800	Description of Human Activity	N/A	24	Occupational Post Application	All	All	Satisfied[8]
870.3465[9]	90-day inhalation toxicity	TGAI	24	Toxicology	All	All	Waived
850.1300	Daphnid chronic toxicity test	TGAI	12	Ecological	All	All	Satisfied[10] DP Barcode: 432638
850.3020[11]	Honey bee acute contact toxicity	TGAI	12	Beneficial insects	All	All	Deficiencies / Data Gap DP Barcode: 432638
850.4225	Seedling emergence, Tier II	TEP	12	Ecological	All	Data are needed only for rice (*Oryza sativa*).	Acceptable DP Barcode: 436254
850.4250	Vegetative vigor, Tier II	TEP	12	Ecological	All	Data are needed only for rice (*Oryza sativa*).	Acceptable DP Barcode: 436254
850.4400[12]	Aquatic plant toxicity test using *Lemna spp.* Tiers I and II	TGAI	12	Aquatic plants	See Footnote 12	See Footnote 12	Deficiencies / Data Gap DP Barcode: 432638

GLN	Study Name	Test Substance	Time Frame (Measured in months from DCI Receipt)	Risk Assessment(s) Data Will Support	Use Site(s) Triggering Anticipated Data Requirement	Applicable Exposure Scenario	Status[18]
850.4500[13,14]	Algal toxicity, Tier II	TGAI	12	Ecological	All	See Footnote 13	Acceptable DP Barcode: 436254
850.4550[14,15]	Algal toxicity, Tier II	TGAI	12	Ecological	All	See Footnote 15	Acceptable DP Barcode: 436254
Special Study[2,16]	Special Aquatic Leaching Study on Wood	TEP	12	Environmental Exposure	Wood treatment	For wood treatment uses only.	Acceptable DP Barcode: 432857
Special Study-ADBAC[17]	Dietary Residue in Food from Treating Hard Surfaces with ADBAC	TEP	12	Dietary	Hard surface products in commercial areas.	Hard surface products in commercial areas.	Acceptable DP Barcode: 435265

TGAI = Technical Grade Active Ingredient; TEP = Typical End-Use Product; N/A = Not Applicable

Footnotes

[1] The GDCI required exposure studies for the following scenarios: Indoor hard surfaces (mop, wipe, trigger pump spray, aerosol spray, and liquid pour); Air deodorization (aerosol spray); carpets (low pressure spray); uses requiring liquid pour of formulated products; humidifier treatment; low and high pressure sprays for disinfectants (such as vehicle treatment); non-pressure treatment of wood (e.g., industrial sapstain treatments, airless sprayer of wood for existing structures); and pressure treatment of wood.

[2] A protocol must be submitted to the Agency for approval prior to the start of the study. The draft protocol was due to the Agency within 90 days of receipt of the DCI.

[3] Data needs for the following scenarios are satisfied: Indoor hard surfaces (mop, wipe, trigger pump spray, aerosol spray, and liquid pour); uses requiring liquid pour of formulated products; pressure treatment of wood, and non-pressure treatment of wood (industrial sapstain treatments).

[4] Data needs for the following scenarios are not satisfied: Non-pressure treatment of wood (airless sprayer for existing structures), low and high pressure sprays for disinfectants (such as vehicle treatment), and carpets (low pressure spray). These studies are within the scope of the Antimicrobial Exposure Assessment Task Force (AEATF) study plan.

[5] The AEATF has conducted an aerosol spray study using a surface spray product; however, this study might not be representative of exposures that occur when using a space spray product for air deodorization. Information regarding the droplet sizes released would be needed for an air deodorization product to determine if exposures could be evaluated using the AEATF Aerosol study.

[6] The GDCI required surface residue studies for the following uses: Carpets, flooring, textiles (laundered clothing/diapers), treated wood; and musical instruments (mouthpiece/reed).

[7] The submitted study addresses hard surfaces, which include flooring. Studies are still needed for carpets, textiles (laundered clothing/diapers), treated wood; and musical instruments (mouthpiece/reed). Without these studies, EPA will default to 100 percent of the application rate as the amount of residue transferred.

[8] The submitted Antimicrobial Exposure Joint Venture (AEJV) National Antimicrobial and Health Care surveys address consumer and medical hard surface uses, respectively. The Health Care Survey could also be used to address hard surface uses in the other commercial, industrial, and institutional market sectors such as food service and food processing.

[9] The Hazard Science Policy Council (HASPOC) met on January 21, 2016 and determined that the ADBAC 90-day inhalation toxicity study is not required due to bridging with the DDAC 28-day inhalation toxicity study (MRID 48667903) (TXR 0057356).

[10] The study is classified as "Supplemental" and cannot be upgraded to "Acceptable" because of several deficiencies noted in the Data Evaluation Record (DER), DP Barcode: 432638. However, even though the study is considered "Supplemental", sufficient data are available for risk assessment. Therefore, no additional data are needed and the guideline is satisfied.

[11] The study must be conducted on antimicrobial wood treatment uses as well as all conventional uses, including mosquito uses.
[12] Data are required if algal studies show toxicity at less than 1 ppm.
[13] Data are required on 3 species: *Navicula pelliculosa, Skeletonema costatum,* and *Selenastrum capricornutum*.
[14] In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. http://www regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028.
[15] Data are required on *Anabaena flosaquae.*
[16] Results from a study conducted according to American Wood Protection Association (AWPA) Standard E11-06 or E11-12 (Standard Method of Determining the Leachability of Wood
Preservatives) will satisfy this data requirement.
[17] A residue transfer protocol must be submitted to the Agency for approval prior to the start of the study. The draft protocol must be submitted to the Agency within 90 days of receipt of this DCI.
[18] Status of the ADBAC Issues Steering Committee/Joint Venture, GDCI response.

3 Human Health Risk Assessment

The Agency anticipates the need to conduct a human health risk assessment for ADBAC. The Agency also anticipates requiring human health data during registration review (as shown in Table 14) and will review data required by the RED DCIs. Based on the memo from the Hazard and Science Policy Council (HASPOC) meeting on January 21st, 2016 (TXR# 0057356[5]), the acute neurotoxicity, subchronic neurotoxicity and the immunotoxicity study requirements have been waived. HASPOC also agreed with the registrant working group proposal to use the 28-day inhalation DDAC study (MRID 48667903) in lieu of conducting an ADBAC 90-day inhalation study.

3.1 Existing Toxicological Endpoints

EPA anticipates the need to re-examine the existing toxicological endpoints as part of this registration review. Table 16 presents the existing endpoints for ADBAC. The endpoints for dietary, dermal, and incidental oral exposure were used in the EPA's human health risk assessment in support of the 2006 RED. Table 16 also includes a new ABDAC inhalation endpoint, determined by bridging data from DDAC (HASPOC memo TXR# 0057356), that was calculated as a Human Equivalent Concentration (HEC) using the LOAEC and regional dose deposition ratio (RDDR) from the 28-day inhalation toxicity study on DDAC. These data will be used in the revised risk assessment for registration review. A detailed description of the toxicity studies is provided in Appendix A.

Table 16 – Existing ADBAC Toxicological Endpoints

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE or UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population; females 13+)	An acute dietary endpoint was not identified in the data base.		
Chronic Dietary	NOAEL =44 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Chronic toxicity/carcinogenicity –rat MRID 41947501 LOAEL = 88 mg/kg/day, based on decreased body weight and weight gain
		Chronic RfD = 0.44 mg/kg/day	
Incidental Oral (short-term)	NOAEL = 10 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental Toxicity – Rat, MRID 42351501 LOAEL = 30 mg/kg/day, based on decreased body weight and food consumption

[5] The HASPOC memorandum (TXR# 0057356) titled *ADBAC: Summary of Hazard and Science Policy Council (HASPOC) Meeting of January 21, 2016: Recommendation on the Requirements for Neurotoxicity (Acute and Subchronic) Studies, Subchronic Inhalation Study and Immunotoxicity study.* can be found in the docket at www.regulations.gov, EPA-HQ-OPP-2006-0339.

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE or UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Incidental Oral (intermediate-term)	NOAEL = 10 mg/kg/day	FQPA SF = 1 UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental Toxicity – Rat, MRID 42351501 LOAEL = 30 mg/kg/day, based on decreased body weight and food consumption
Short-Term Dermal	NOAEL= 20 mg ai/kg/day (333 µg/cm^2)	FQPA SF = 1 UF = 10 (3x inter-species extrapolation, 3x intra-species variation)	21-day dermal toxicity- guinea pigs MRID 41105801 LOAEL = 40 mg ai/kg/day, based on denuded non-vascularized epidermal layer
Intermediate-Term Dermal	NOAEL = 20 mg ai/kg/day (80 µg/cm^2)	UF = 10 (3x inter-species extrapolation, 3x intra-species variation)	90-day dermal toxicity in rats MRID 41499601 20 mg ai/kg/day is the highest dose tested before irritation became significant at day 43
Long-Term Dermal (TGAI)	No appropriate endpoint identified. No systemic effects observed up to 20 mg/kg/day, highest dose of technical grade that could be tested without irritation effects.		
Inhalation (short and intermediate term)	LOAEC < 0.08 mg/m^3 (HEC = 0.018 mg/m^3)	UF = 100 (3x inter-species extrapolation, 10x intra-species variation, 3X NOAEC to LOAEC conversion)	28-day DDAC inhalation toxicity – rat, MRID 48667903 LOAEC = 0.08 mg/m^3, based on ulceration of the nasal cavity, degeneration of the olfactory epithelium, increase in mucoid production and decreased body weight/weight gain in males RDDR = 0.298 (Extrathoracic Effects)
Inhalation (Long term)	LOAEC < 0.08 mg/m^3 (HEC = 0.018 mg/m^3)	UF = 300 (3x inter-species extrapolation, 10x intra-species variation, 3X NOAEC to LOAEC conversion, 10X duration)	28-day DDAC inhalation toxicity – rat, MRID 48667903 LOAEC = 0.08 mg/m^3, based on ulceration of the nasal cavity, degeneration of the olfactory epithelium, increase in mucoid production and decreased body weight/weight gain in males RDDR = 0.298 (Extrathoracic Effects)

HEC = LOAEC (0.08 mg/m^3) * (6 hours/day Rat Exposure /8 hours/day Human Exposure) * RDDR (0.298)

3.2 Dietary Exposure

The last dietary exposure assessment was conducted in 2006 for the ADBAC RED. EPA anticipates the need to conduct a revised dietary exposure (food and drinking water) assessment to support registration review of ADBAC since there are multiple labeled uses that could result in both direct and indirect food contact, and the dietary exposure assessment policies have been updated since 2006. The registered antimicrobial uses of ADBAC that result in dietary exposure include: (1) as a sanitizer/disinfectant in/around agricultural premises and equipment; (2) a sanitizer/disinfectant for food contact surfaces in food handling establishments/food processing plants, residential areas, and commercial areas; (3) as a materials preservative in polymers and

adhesives; (4) as a slimicide in paper production; and (5) as an egg wash. The registered antimicrobial uses of ADBAC that result in human drinking water exposure include: (1) ice machines; (2) water holding tanks; and (3) Reverse Osmosis (RO) units. The registered conventional uses of ADBAC that could potentially result in human drinking water exposure include turf, lawns and golf courses.

3.2.1 Food

Dietary exposure assessments will be conducted during registration review since currently registered antimicrobial uses of ADBAC may result in dietary (food) exposure. Screening-level dietary assessments were conducted to determine anticipated data needed for the registration review of ADBAC (see Table 14). The Agency has determined that none of the conventional uses of ADBAC are likely to result in dietary (food) exposure.

A screening-level chronic (food only) dietary exposure assessment was conducted for registration review using established toxicological points of departure (PODs). An acute dietary exposure assessment was not conducted because an acute POD was not identified from existing data. The chronic population adjusted dose (cPAD) is 0.44 mg/kg/day.

A summary of the registered uses of ADBAC with the potential to result in dietary (food only) exposure is provided in Table 17. A residue study is available that shows the reduction of ADBAC residues from hard surfaces following a potable water rinse (PWR), or the rinsing of a hard non-porous surface with water that is potable (MRID 46870704). The results of the study indicate that after an ADBAC solution is sprayed or wiped onto a hard surface as a disinfectant, the residues are reduced by 52% from a PWR.

Additionally, a study is available that quantifies the transfer of ADBAC residues to food when food (represented by apples, bread, and bologna) contacts hard surfaces treated with ADBAC (MRID 46870703). The results of the study indicate that after treating a hard surface with ADBAC, up to 44.3% of residues may transfer to food. This represents the most conservative estimate of transferability and was generated from the bologna food samples.

Therefore, the screening-level chronic dietary exposure assessment was conducted using the maximum amount of refinement available based on chemical-specific residue estimates where appropriate (i.e., incorporating residue reductions with a PWR and incorporating a reduction to account for residue loss from transfer of ADBAC from hard surfaces to food).

Table 17 – Summary of Registered ADBAC Uses Expected to Result in Dietary (Food Only) Exposure

158W Use Site Category	Highest Labeled Concentration (ppm)	Representative EPA Reg. No.	PWR Adjustment[1]	Transferability Adjustment[6]
Food Handling/Storage Establishments, Premises and Equipment[3]	16,000	80346-1	Yes	Yes
Commercial, Institutional and Industrial Premises and Equipment	16,000	80346-1	Yes	Yes
	4900	70488-1	No[4]	Yes

158W Use Site Category	Highest Labeled Concentration (ppm)	Representative EPA Reg. No.	PWR Adjustment[1]	Transferability Adjustment[6]
Residential and Public Access Premises	16,000	80346-1	No[7]	No[7]
	4900	70488-1	No[4]	No[8]
Paper – Slimicides	3.3 lb ai/ton paper	10324-188	No[2]	No
Paper – Process Water[5]	246 ppm	10324-185	No[2]	No
Egg Wash	400	10324-111	No[2]	No

1. Available study results indicate that 52% of ADBAC residues will remain on surfaces following a potable water rinse after application. The highest maximum residue levels on all registered labels containing ADBAC have been corrected for this reduction when applicable. Residue value (mg) = AoS (Active on Surface = 1 mg/cm^2 * µg/g * 1g/1,000,000 µg)* Area of Treated Surface (cm^2) * Fraction Remaining on the Surface (48%)
2. Treatments not requiring a potable water rinse or for which a potable water rinse is not applicable.
3. Dietary (food only) exposure assessment for food handling/storage establishments, premises and equipment is represented by the "commercial areas" dietary exposure assessment.
4. Potable water rinse not on the label.
5. Label directions indicate 3.93 lbs of product per short ton of paper = 246 ppm ai in the slurry water (3.93 lbs * 12.5% ADBAC ÷ 0.002 lb/ton = 246 ppm).
6. Residue values adjusted for transferability data (MRID 46870703) indicating that up to 44.3% of ADBAC residues may transfer to food from hard surfaces.
7. No risk estimates of concern identified using IDREAM and the maximum concentration listed on the label; therefore additional PWR and transferability refinements were not incorporated.
8. No risk estimates of concern identified using IDREAM and the maximum concentration listed on the label; therefore additional transferability refinements were not incorporated.

Animal premises and equipment were listed as "non-food" in the use site data tables provided by the ADBAC Issues Steering Committee/Joint Venture. The Agency relied on the information provided by the Committee in this screening assessment. The Agency considers uses on animal premises "non-food" if the labels state the following restriction:

Prior to use of this product, remove all animals {poultry} and feeds from [{premises} {areas to be treated}], animal transportation vehicles {trucks, cars}, and enclosures [{coops, crates, kennels, stables}]. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other surfaces of facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean surfaces with soap or detergent and rinse with water.

Registrants whose ADBAC product labels do not currently bear the language above regarding animal premises and wish their products to be considered non-food must amend their labels accordingly with the Agency. ADBAC registrants who do not take action to make this change should anticipate that the Agency will assume that labels claiming an animal premise use are direct or indirect food use per the Antimicrobial Use Site Index (USI) (https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-use-site-index). Product designations of direct or indirect food use may result in conservative assumptions in the risk assessment.

Although some labels allow active ingredient concentrations of up to 16,000 ppm on hard surfaces that may contact food, this concentration is greater than the currently established tolerance exemption of 200 or 400 ppm for food contact/hard surfaces in commercial areas. Therefore, for hard surfaces in commercial areas, in addition to using the label rates, the dietary exposure assessment was also conducted using the established tolerance exemption level of 400 ppm.

For dietary (food only) scenarios, a total estimated daily dietary intake (TEDDI) assessment is usually conducted to determine whether additional toxicity data (chronic/carcinogenicity studies) are required; however, there are acceptable chronic/carcinogenicity studies available for ADBAC (see Appendix A). Therefore, an additional study is not required at this time and a TEDDI assessment has not been conducted for any dietary exposure scenarios.

Dietary Exposure Assessment – Residential Areas

Assuming the highest labeled rate (16,000 ppm)

A residential exposure assessment for hard surface products was conducted using the Indirect Dietary Residential Exposure Assessment Model (IDREAM), which is a refined Tier II model. The chronic dietary (food only) exposure and risk estimates do not exceed the level of concern (LOC) [i.e., < 100% of the PAD] for the U.S. Population or any population subgroups.

Table 18 – Chronic Exposure Assessment for Use of ADBAC in Residential Areas – IDREAM (16,000 ppm)

Population Group	Exposure[1]	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
General U.S. Population	0.0660	15
All Infants (<1 year old)	0.0487	11
Children 1-2 years old	**0.188**	**43**
Children 3-5 years old	0.159	36
Children 6-12 years old	0.101	23
Youth 13-19 years old	0.0605	14
Adults 20-49 years old	0.0543	12
Adults 50-99 years old	0.0497	11
Females 13-49 years old	0.0519	12

[1] Active on Surface (mg/cm^2) x surface area (2000 cm^2) x fraction transferred (100%) ÷ BW (kg)
The most highly exposed population subgroup is in bold.

Assuming the highest labeled rate without a PWR (4,900 ppm)

Some registered labels do not require a PWR. Therefore, a residential exposure assessment for hard surface products was conducted at the highest labeled rate (4,900 ppm and 0.49% ai) without a PWR using IDREAM. The chronic dietary (food only) exposure and risk estimates do not exceed the level of concern (LOC) [i.e., < 100% of the PAD] for the U.S. Population or any population subgroups.

Table 19 – Chronic Exposure Assessment for Use of ADBAC in Residential Areas without a PWR – IDREAM (4900 ppm)

Population Group	Exposure[1]	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
General U.S. Population	0.0202	4.6
All Infants (<1 year old)	0.0149	3.4
Children 1-2 years old	**0.0577**	**13**
Children 3-5 years old	0.0487	11
Children 6-12 years old	0.0309	7.0
Youth 13-19 years old	0.0185	4.2

Population Group	Exposure[1]	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
Adults 20-49 years old	0.0166	3.8
Adults 50-99 years old	0.0152	3.5
Females 13-49 years old	0.0159	3.6

[1] Active on Surface (mg/cm^2) x surface area (2000 cm^2) x fraction transferred (44.3%) ÷ BW (kg)
The most highly exposed population subgroup is in bold.

Dietary Exposure Assessment – Commercial Areas

Assuming the highest labeled rate, a PWR (MRID 46870704), and maximum transfer from treated hard surfaces to food (44.3%) (MRID 46870703)

In commercial areas, the chronic dietary (food only) exposure and risk estimates exceed the LOC [i.e., >100% of the PAD] for the U.S. Population, all infants < 1 year old, children 1-2 years old, children 3-5 years old, and children 6-12 years old when using the Commercial Tier 1B model for food contact (hard surfaces). This incorporates residue adjustments for the potable water rinse specified on the product labels and accounts for transfer of residues from treated hard surfaces to food as described above.

Table 20 – Chronic Exposure Assessment for Use of ADBAC in Commercial Areas Assuming Highest Labeled Rate (16000 ppm, with 48% Transfer from PWR, and 44.3% Transfer from Hard Surfaces to Food)

Population Group	Exposure[1]	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
General U.S. Population	0.1938598	44
All Infants (<1 year old)	1.7673974	**400**
Children 1-2 years old	1.0800762	**250**
Children 3-5 years old	0.7277519	**170**
Children 6-12 years old	0.3668183	83
Youth 13-19 years old	0.2022134	46
Adults 20-49 years old	0.1669811	38
Adults 50-99 years old	0.1675980	38
Females 13-49 years old	0.1866798	42

[1] Exposure = Active on Surface (mg/cm^2) x surface area (4000 cm^2) x fraction transferred (44.3%) ÷ BW (kg). Active on Surface (mg/cm^2) = [Residual Solution (mg/cm^2) x Active Ingredient Concentration (ppm) x PWR Adjustment (48%)] x 1g/1,000,000 mg
The most highly exposed population subgroup is in bold.

Assuming the highest labeled rate without a PWR and maximum transfer from treated hard surfaces to food (44.3%) (MRID 46870703)

Some registered labels do not require a PWR. Therefore, a commercial exposure assessment for hard surface products was conducted at the highest labeled rate (4,900 ppm), assuming 44.3% transfer from hard surfaces to food, and without accounting for a PWR. In commercial areas, the chronic dietary (food only) exposure and risk estimates exceed the LOC [i.e., >100% of the PAD] for all infants (<1 year old), children 1-2 years old, children 3-5 years old, and children 6-12 years old when using the Commercial Tier 1B model for food contact (hard surfaces).

Table 21 – Chronic Exposure Assessment for Use of ADBAC in Commercial Areas Assuming Highest Labeled Rate (4900 ppm) without a PWR and 44.3% Transfer from Hard Surfaces to Food

Population Group	Exposure[1]	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
General U.S. Population	0.124	28
All Infants (<1 year old)	**1.128**	**260**
Children 1-2 years old	0.689	160
Children 3-5 years old	0.464	110
Children 6-12 years old	0.234	53
Youth 13-19 years old	0.129	29
Adults 20-49 years old	0.107	24
Adults 50-99 years old	0.107	24
Females 13-49 years old	0.119	27

[1] Exposure = Active on Surface (mg/cm^2) x surface area (4000 cm^2) x fraction transferred (44.3%) ÷ BW (kg). Active on Surface (mg/cm^2) = [Residual Solution (mg/cm^2) x Active Ingredient Concentration (ppm)] x 1 g/1,000,000 mg
The most highly exposed population subgroup is in bold.

Assuming the tolerance exemption of 400 ppm

In commercial areas, the chronic dietary (food only) exposure and risk estimates are not of concern [i.e., <100% of the PAD] for the U.S. population and all population subgroups when using the Commercial Tier 1A model for food contact (hard surfaces). This assessment assumes no PWR but maximum transfer from hard surfaces to food (44.3%).

Table 22 – Chronic Exposure Assessment for Use of ADBAC in Commercial Areas Assuming Tolerance Exemption (400 ppm) without a PWR and 44.3% Transfer from Hard Surfaces to Food

Population Group	Exposure[1]	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
General U.S. Population	0.0101	2.3
All Infants (<1 year old)	**0.0921**	**21**
Children 1-2 years old	0.0563	13
Children 3-5 years old	0.0379	8.6
Children 6-12 years old	0.0191	4.3
Youth 13-19 years old	0.0105	2.4
Adults 20-49 years old	0.00877	2.0
Adults 50-99 years old	0.00873	2.0
Females 13-49 years old	0.00972	2.2

[1] Exposure = Active on Surface (mg/cm^2) x surface area (4000 cm^2) x fraction transferred (44.3%) ÷ BW (kg). Active on Surface (mg/cm^2) = [Residual Solution (mg/cm^2) x Active Ingredient Concentration (ppm)] x 1 g/1,000,000 mg
The most highly exposed population subgroup is in bold.

Dietary Exposure Assessment – Paper Production

There are multiple end-use products for ADBAC use in paper production that may result in indirect food contact to ADBAC. The results have been presented here for ADBAC use as a slimicide during paper production and for use in paper plant process water.

Paper Mold Inhibition – Slimicide

The screening-level dietary risk assessment for ADBAC as a slimicide during paper production at a rate of 3.3 lb ai/ton of paper (EPA Reg. No. 10324-188) indicates that chronic dietary (food only) exposure and risk estimates are not of concern [i.e., <100% of the PAD] for the U.S. population and all population subgroups.

Table 23 – Chronic Exposure Assessment for Use of ADBAC as a Slimicide in Papermaking – lb ai/ton Paper

Population Subgroup	BW (kg)	Total Food Consumed (g)	DC (µg ai/g food)	EDI (µg ai/person/day)	DDD (mg/kg/day)	% cPAD
General U.S. Population	70.2	3910	0.00338	13.2	0.000188	<1
All Infants (<1 year old)	7.7	766		2.59	0.000338	<1
Children 1-2 years old	12.6	1770		5.99	0.000475	<1
Children 3-5 years old	18.7	1940		6.56	0.000351	<1
Children 6-12 years old	37.1	2460		8.32	0.000224	<1
Youth 13-19 years old	67.3	3050		10.3	0.000153	<1
Adults 20-49 years old	81.5	4110		13.9	0.000171	<1
Adults 50-99 years old	81.2	3780		12.8	0.000158	<1
Females 13-49 years old	72.9	3680		12.5	0.000171	<1

BW = Bodyweight; Mean weights from NHANES WWEIA 2003-2008
DC = Dietary concentration
EDI = Estimated daily intake = DC*Total Food Consumed
DDD = Daily dietary dose = (EDI*1 mg/1000 µg)/BW
%cPAD = % chronic Population-Adjusted Dose = (DDD/cPAD)*100%

Paper – Process Water

The screening-level dietary risk assessment for ADBAC as a mold inhibitor in paper production process water at a rate of 246 ppm (EPA Reg. No. 10324-185) indicates that chronic dietary (food only) exposure and risk estimates are not of concern [i.e., < 100% of the PAD] for the U.S. population and all population subgroups.

Table 24 – Chronic Exposure Assessment for Use of ADBAC as a Slimicide in Papermaking – Process Water

Population Subgroup	BW (kg)	Total Food Consumed (g)	DC (µg ai/g food)	EDI (µg ai/person/day)	DDD (mg/kg/day)	% cPAD
General U.S. Population	70.2	3910	0.4595	1797	0.0256	5.8
All Infants (<1 year old)	7.7	766		352	0.0457	10
Children 1-2 years old	**12.6**	**1770**		**813**	**0.0645**	**15**
Children 3-5 years old	18.7	1940		891	0.0477	11
Children 6-12 years old	37.1	2460		1130	0.0305	7.0
Youth 13-19 years old	67.3	3050		1401	0.0208	4.7
Adults 20-49 years old	81.5	4110		1889	0.0232	5.3
Adults 50-99 years old	81.2	3780		1737	0.0214	4.9
Females 13-49 years old	72.9	3680		1691	0.0232	5.3

BW = Bodyweight; Mean weights from NHANES WWEIA 2003-2008
DC = Dietary concentration
EDI = Estimated daily intake = DC*Total Food Consumed
DDD = Daily dietary dose = (EDI*1 mg/1000 µg)/BW
%cPAD = % chronic Population-Adjusted Dose = (DDD/cPAD)*100%

Dietary Exposure Assessment – Egg Wash

There are multiple products containing ADBAC that allow use as an egg-shell sanitizer. Therefore, a screening-level chronic dietary (food-only) exposure analysis was completed to evaluate the direct treatment of egg shells using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

For a chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food-commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

The maximum allowed residue on eggshells found on all registered ADBAC labels based on information provided by the ADBAC/DDAC Issues Steering Committee/Joint Venture was 400 ppm. Therefore, a residue value of 400 ppm was entered into DEEM for all egg commodities. The screening-level dietary risk assessment indicates that chronic dietary (food only) exposure and risk estimates are of concern [i.e., >100% of the PAD] for children 1-2 years old; the U.S. population and all other population subgroups are not of concern.

Table 25 – Chronic Exposure Assessment for Use of ADBAC as an Egg Wash (400 ppm)

Population Group	Exposure	Risk Estimates
	Exposure (Dose) (mg/kg/day)	% cPAD
General U.S. Population	0.161	37
All Infants (<1 year old)	0.123	28
Children 1-2 years old	**0.507**	**120**
Children 3-5 years old	0.380	86
Children 6-12 years old	0.215	49
Youth 13-19 years old	0.114	26
Adults 20-49 years old	0.133	30
Adults 50-99 years old	0.138	31
Females 13-49 years old	0.117	27

The most highly exposed population subgroup is in bold.

Dietary Exposure Assessment – Conclusions

The chronic dietary exposure assessment for the registered uses of ADBAC at the maximum labeled rates are of concern, even when incorporating available data on transferability of residues from treated hard surfaces to food and data on reduction of residues following a potable water rinse, where applicable. However, the Agency does not anticipate the need to call in any additional data for indirect food uses at this time since chemical specific data representing a PWR as well as migration data have previously been submitted/reviewed and incorporated into the assessments herein. During the registration review process, additional refinements to the

dietary exposure assessment may be performed to further refine estimated exposures from the indirect food uses of ADBAC. The Agency notes that the product use rates assessed for commercial areas (16000 ppm with a PWR and 4900 ppm without a PWR) are both well-above the established tolerance exemption level for ADBAC.

Because the use on eggs is considered a direct food use and results in risks of concern, magnitude of the residue data on eggs are required (OCSPP Guideline 860.1480). The use on eggs will be reassessed when data are submitted. Supporting storage stability data (OCSPP Guideline 860.1380) as well as a residue analytical method for data collection (OCSPP Guideline 860.1340) are also required. These anticipated data needs are listed in Section 2, Table 14.

3.2.2 Drinking Water

A drinking water assessment was not conducted in 2006 as part of the RED for ADBAC. The Agency determined at that time that the registered antimicrobial uses of ADBAC were not expected to significantly impact surface or ground water resources. The following uses of ADBAC may result in drinking water exposure from surface water downstream of Waste Water Treatment Plants (WWTPs): cooling tower water systems; air washers; pulp and paper mills; down-the-drain exposure from hospital and swimming pool uses; wood preservative uses; and turf, golf course, and ornamental uses. In the absence of environmental fate data on sorption to activated sludge and toxicity to WWTP microorganisms, the Agency assumes that these uses can result in continuous exposure to surface water at low concentrations even though the primary route of dissipation of ADBAC in the aquatic environment is sorption to sediment (bottom and suspended) (MRID 40835604 and 41105501). If WWTP environmental fate and effects data required for registration review demonstrate high removal by sorption to sludge and a relatively low toxicity to WWTP microorganisms, the Agency does not anticipate conducting a drinking water risk assessment from ADBAC in surface water downstream of WWTPs. However, in the absence of the WWTP studies or if the submitted data do not demonstrate high removal by sorption to sludge and a relatively low toxicity to WTTP microorganisms, the Agency will conduct a drinking water assessment.

Other potential sources of human exposure to drinking water are from registered antimicrobial uses of ADBAC added to the interior of ice machines and the interior of water holding tanks, as well as application to Reverse Osmosis units in water holding tanks. The registered conventional uses of ADBAC that could potentially result in human drinking water exposure include turf, lawns and golf courses. A dietary risk assessment will include drinking water from these other potential sources and food uses.

3.3 Occupational and Residential Exposures

The Agency anticipates the need to revise the occupational and residential assessments conducted for the antimicrobial and conventional uses in support of the 2006 RED since the Margins of Exposures (MOEs) were calculated using toxicological point of departures (PODs) and exposure data that have since been updated. In particular, it will be necessary to reassess the inhalation exposures using the HEC of 0.018 mg/m^3 from the DDAC inhalation toxicity study

(see Table 16) that was submitted after the RED. In addition, ADBAC's RED required label changes to mitigate occupational and residential exposures include the following:

- Add re-entry interval (REI) of 2 hours to all labels listing hatcheries fogging as a use.
- Add REI of 2 hours as well as a minimum of 4 air exchanges (ACH) per hour in the facility to all labels listing food processing plants fogging as a use.
- Add restriction that swimming pool use products must not be applied when swimmers are in the immediate vicinity. Add REI of 15 minutes to all labels listing swimming pools as a use.

The Agency anticipates that some mitigation measures may change due to changes in ADBAC's toxicological endpoints. The uses of ADBAC that may result in occupational and residential handler and post-application exposures are presented in Table 26, 27, 28 and 29. These tables include exposure scenarios for both the antimicrobial and conventional uses of ADBAC.

3.3.1 Occupational Handler Exposure

EPA anticipates the need to revise the occupational handler assessment conducted in support of the 2006 RED. In response to the need for indoor dermal and inhalation exposure data for antimicrobial chemicals, the Antimicrobial Exposure Assessment Task Force II (AEATF II) has completed exposure studies for several scenarios including liquid pour, solid pour, trigger spray and wipe, aerosol can application, mopping and pressure treatment wood preservation. These studies have been reviewed by the Agency in conjunction with the Human Studies Review Board and have been found to be ethically and scientifically acceptable for use in risk assessment. The data from these studies will be used to assess occupational and residential handler exposures for antimicrobial chemicals. In addition, two sapstain worker exposure studies (MRID 45524304 and 47618301) sponsored by the Sapstain Industry Group (SIG) were previously submitted to EPA and will be used to assess occupational handler exposures during sapstain treatment. In addition, the inhalation component of the SIG study was conducted for comparison to the inhalation toxicity endpoint that existed at the time of the study (the oral NOAEL of 8 mg/kg/day) and thus the LOD of 5.8 ug/m^3 that was used may not be low enough to allow assessment of exposures to the revised HEC of 0.018 mg/m^3 (18 ug/m^3) that is based on the inhalation toxicity study.

To assess occupational handler exposures for the conventional uses, the Agency will use the unit exposure data listed in the Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (US EPA, 2015). This table includes exposure data from the Agricultural Handler Exposure Task Force (AHETF) and the Outdoor Residential Exposure Task Force (ORETF).

It should be noted that data from the AHETF, ORETF, AEATF II and SIG are subject to data compensation. The occupational handler scenarios to be assessed are presented in Table 26.

Table 26 – Occupational Handler Exposure Scenarios for ADBAC

Scenario	Exposure Routes	Duration
Antimicrobial Uses		
Open pour for industrial process and water systems treatment	Dermal, Inhalation	Short and Intermediate Term
Wood Preservation – Pressure Treatment	Dermal, Inhalation	Short, Intermediate, and Long Term
Wood Preservation – Spray or dip treatment for sapstain control	Dermal, Inhalation	Short, Intermediate, and Long Term
Wood Preservation – Spray treatment of existing shingle and shake structures	Dermal, Inhalation	Short and Intermediate Term
Hard surface disinfection using low pressure handwands, high pressure handwands, aerosol cans, trigger sprayers, mops and wipes.	Dermal, Inhalation	Short, Intermediate, and Long Term
Hard surface disinfection using handheld foggers or misters	Dermal, Inhalation	Short and Intermediate Term
Conventional Uses		
Mosquito Control in Ornamental Ponds and Fountains – Open pour liquid	Dermal, Inhalation	Short and Intermediate Term
Turf, Sod-farm - Mix/load liquids, mix/load wettable powder, ground boom application	Dermal, Inhalation	Short and Intermediate Term
Turf, Golf Course, Residential, and Commercial – Mix/load liquids, mix/load wettable powder, ground boom application, mechanically pressurized handwand application	Dermal, Inhalation	Short and Intermediate Term
Ornamental Herbaceous Plants, Shrubs, and Trees - Mix/load liquids, mix/load wettable powder, mechanically pressurized handwand application, manually pressurized handwand application, airblast sprayer application	Dermal, Inhalation	Short and Intermediate Term
Seedlings after Planting– Mix/load liquids, mix/load wettable powder, ground boom application, mechanically pressurized handwand application, manually pressurized handwand application	Dermal, Inhalation	Short and Intermediate Term
Carnations - Mix/load liquids, mix load wettable powder ground boom application, mechanically pressurized handwand application, manually pressurized handwand application	Dermal, Inhalation	Short and Intermediate Term
Seedlings Before Planting, Cuttings and Bulbs – Dip Treatment	Dermal, Inhalation	Short and Intermediate Term

3.3.2 Occupational Post Application Exposures

EPA anticipates the need to revise the occupational post application exposure assessment conducted in support of the 2006 RED. No additional data is needed to assess post application exposures for the antimicrobial uses of ADBAC. To assess post application exposures for the conventional uses, a turf transferable residue (TTR) study (Guideline #875.2100) is anticipated to be needed. The occupational post-application exposure scenarios to be assessed are presented in Table 27.

Table 27 – Occupational Post-Application Exposure Scenarios for ADBAC

Scenario	Exposure Routes	Duration
Antimicrobial Uses		
Post Application Exposure to fogging treatments	Inhalation	Short, Intermediate, and Long Term
Conventional Uses		
Post Application to Turf	Dermal	Short and Intermediate Term
Post Application to Ornamentals	Dermal	Short and Intermediate Term

3.3.3 Residential Handler Exposures

EPA anticipates the need to revise the residential handler assessment conducted in support of the 2006 RED. To assess residential handler exposures for the antimicrobial uses of ADBAC, the Agency will use the data from AEATF as discussed above for occupational handlers. To assess residential handler exposures for the conventional uses of ADBAC, the Agency will use the unit exposures from the Standard Operating Procedures for Residential Pesticide Exposure Assessment (US EPA, 2012). The residential handler exposure scenarios that will be evaluated are listed in Table 28.

Table 28 – Residential Handler Exposure Scenarios for ADBAC

Scenario	Exposure Routes	Duration
Antimicrobial Uses		
Hard surface disinfection using aerosol cans, trigger sprayers, mops and wipes	Dermal, Inhalation	Short, Intermediate, and Long Term
Soft surface sanitization of carpets using low pressure sprayers	Dermal, Inhalation	Short Term
Air freshener treatments using aerosol can	Inhalation	Short, Intermediate, and Long Term
Open pour for pool and spa treatment	Dermal, Inhalation	Short Term
Wood Preservation – Spray and brush treatment of existing shingle and shake structures	Dermal, Inhalation	Short Term
Conventional Uses		
Residential turf and ornamental plants and shrubs - Mix /Load /Apply liquid using a manually pressurized handwand, hose end sprayer, or backpack sprayer	Dermal, Inhalation	Short Term
Residential turf and ornamental plants and shrubs - Mix /Load /Apply wettable powder using a manually pressurized handwand, hose end sprayer, or backpack sprayer	Dermal, Inhalation	Short Term
Cutting and bulbs – Dip Treatment	Dermal, Inhalation	Short Term

3.3.4 Residential Post-Application Exposures

EPA anticipates the need to revise the residential post-application assessment conducted in support of the 2006 RED. To assess post application exposures for the antimicrobial uses, a post application inhalation exposure study (Guideline #875.2500) is anticipated to be needed. This study is needed to assess inhalation exposures resulting from the use of ADBAC in humidifier water. A post application inhalation exposure study (MRID 47222901) for the humidifier use was submitted after the RED, however, the LOQ of 0.026 mg/m^3 is not low enough to permit comparison to the HEC of 0.018 mg/m^3 which has a target MOE of 100. In addition, the application rate of 100 ppm used in the study is less than the maximum application rate of 510 ppm allowed by the labels. A new study needs to be conducted with an LOQ of 0.00018 mg/m^3 to allow for comparison to the HEC and this study should be done at an application rate of 510 ppm. To assess post application exposures for the conventional uses, a turf transferable residue (TTR) study (Guideline #875.2100) is anticipated to be needed. The residential post-application exposure scenarios to be assessed are presented in Table 29.

Table 29 – Residential Post-Application Exposure Scenarios for ADBAC

Exposed Population	Exposure Scenario	Exposure Routes	Duration
Antimicrobial Uses			
Children	Mouthing treated laundry	Incidental Oral	Short and Intermediate Term
Children	Playing on decking and playground equipment	Dermal, Incidental Oral	Short and Intermediate Term
Children	Playing on treated floors and carpets	Dermal, Incidental Oral	Short and Intermediate Term
Children and Adults	Humidifier Treatment	Inhalation	Short and Intermediate Term
Children and Adults	Air freshener treatments	Inhalation	Short and Intermediate Term
Children and Adults	Swimming in treated pools	Dermal, Incidental Oral	Short and Intermediate Term
Children and Adults	Wearing treated laundry	Dermal	Short and Intermediate Term
Conventional Uses			
Children	Playing on Treated Turf	Incidental Oral	Short Term
Children and Adults	Residential Turf	Dermal	Short Term
Adults	Ornamentals	Dermal	Short Term

3.4 Aggregate and Cumulative Exposure

3.4.1 Aggregate Exposures

EPA anticipates the need to revise the aggregate assessment conducted in support of the 2006 RED. Aggregate exposures will need to be assessed upon reevaluation of the aggregate assessment and toxicological endpoints, combined with the human health exposure assessments

expected as a part of this registration review case. This assessment will include dietary (food and water) exposures and residential exposures.

3.4.2 Cumulative Exposures

In 2015, EPA's Office of Pesticide Programs released a guidance document entitled, Pesticide Cumulative Risk Assessment: Framework for Screening Analysis. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. In May 2016, a final version of this guidance document was released (U.S. EPA, 2016) stating that non-specific toxic effects, such as irritation, unless tied to a mode of action (MOA)/adverse outcome pathway (AOP) or testable hypothesis related to a potential MOA/AOP, would not support a candidate common mechanism group (CMG). This framework supplements the existing guidance documents for establishing common mechanism groups[6] and conducting cumulative risk assessments.[7]

The Agency has utilized this framework for ADBAC and notes that irritation endpoints are not considered for cumulative assessments for ADBAC and any other substances. Also, ADBAC does not appear to produce a toxic metabolite produced by other substances. The Agency notes that the individual exposure scenarios in ADBAC assessments are developed by summing the total percent of ADBAC active ingredients on a product's label. For the purposes of this registration review, the Agency is not conducting a cumulative assessment. For information regarding the Agency's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see http://www.epa.gov/pesticides/cumulative/.

4 Environmental Risk Assessment

The Agency has not previously conducted a risk assessment that supports a complete endangered species determination for ADBAC. At this time the Agency anticipates that, as part of registration review, an ecological risk assessment will be needed for ADBAC based on the uses of ADBAC in cooling tower water systems; air washers; pulp and paper mills; down-the-drain exposure from hospital and swimming pool uses; wood preservative uses; and turf, golf course, and ornamental uses. The ecological risk assessment planned during registration review will allow the Agency to determine potential acute and chronic risks to aquatic organisms exposed to residues of ADBAC that are transported from treatment sites into the aquatic environment.

Such sites include: cooling tower water systems; air washers; pulp and paper mills; down-the-drain exposure from hospital and swimming pool and spa uses; wood preservatives; and turf, golf course, and ornamental uses. There is potential for acute exposure to aquatic organisms in the water column because of the high solubility of ADBAC in water (Table 4). However, bioconcentration in aquatic organisms is not expected despite the high log K_{ow} of 3.91 (>3)

[6] Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity (U.S. EPA, 1999)
[7] Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity (U.S. EPA, 2002)

because ADBAC is highly soluble in water and, being a positively-charged compound, is tightly sorbed to soil and sediment, which are typically negatively-charged. Chronic exposure to sediment-dwelling organisms from both antimicrobial and conventional uses is expected to occur based on the sorption potential from the positively-charged parent compound. Potential acute and chronic risks to terrestrial as well as aquatic organisms will be assessed for the conventional uses (*e.g*. applications to turf and golf courses) of ADBAC.

The risk assessment also will allow the Agency to determine whether each use of the ADBAC has 'no effect' or 'may affect' federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use 'may affect' a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Services (the Services), as appropriate.

4.1 Environmental Fate Assessment

ADBAC is completely soluble in water, and based on its low vapor pressure and Henry's Law value (Table 4), is not expected to partition from soil and water into air. ADBAC is stable to hydrolysis at pH values of 5, 7, and 9 (MRID 40835602), with half-lives ranging from 150 to 379 days, and stable to photodegradation in pH 7 buffered aqueous solutions, but degraded in water in the presence of a photosensitizer with a half-life of 7 days (MRID 40835603). ADBAC is stable to microbial degradation under aerobic and anaerobic conditions in water and sediment (MRID 40835604, 41105501, and 42415101). ADBAC is reported to be readily biodegradable in an aerobic aqueous medium over time (MRID 46865601); however, these results contradict the persistence of ADBAC demonstrated in the aerobic aquatic metabolism study (MRID 40835604). This may be due to ADBAC sorbing to sediment present in the aquatic metabolism study, resulting in stabilization of ADBAC. In the absence of sediment, ADBAC biodegraded during the course of the ready biodegradability study. Data relevant to aerobic soil metabolism have not been submitted and are anticipated to be required for conventional uses. Sorption to soil, sediment, and sludge is expected to be the primary route of dissipation from water based on the fact that this is a quaternary ammonium compound with a positive electrical charge that will sorb to negatively-charged (*e.g.*, clay) particles. In soil and sediment, ADBAC is expected to be immobile based on the Freundlich K_{ads} values of 5,123 – 32,429 L/kg and K_{oc} values of 640,389 – 6,171,657 L/kg_{oc}[8] (MRID 40835605 and 42414801). Because of its strong sorption to soils, ADBAC is not expected to leach to ground water or be present in dissolved form in runoff water discharged to surface water. ADBAC, however, is expected to be associated with the eroded sediment that is transported during runoff. There are no major degradates of ADBAC based on its stability to microbial metabolism in the environment.

4.1.1 Leaching (Treated Wood)

Based on similar chemical and physical properties of ADBAC and DDAC, bridging of wood leaching data between these two active ingredients is appropriate. A study done on DDAC (MRID 49812403) demonstrated leaching rates for DDAC from treated blocks were essentially

[8] Based on the Food and Agriculture Organization of the United Nations (FAO) soil classification of mobility, http://www.fao.org/docrep/003/x2570e/x2570e06 htm

proportional to the treatment rate of the wood. At the end of a 14-day period the total amount of DDAC leached ranged from 2.6-8.2%, with maximum leach rates of 1,219-13,330 ug/cm^2/day at 0.8-3.2 % w/w.

4.1.2 Wastewater Treatment Plants (WWTPs)

If the Activated Sludge Sorption Isotherm (ASSI) study does not demonstrate a strong potential to sorb during activated sludge treatment, the Agency may require verification of results from the ready biodegradability study (MRID 46865601) or an appropriate WWTP biodegradability study as determined by the results of the Activated Sludge Respiration Inhibitor (ASRI) test. The Agency received a ready biodegradability study (MRID 46865601) that was classified as upgradeable rather than acceptable and the results contradicted the persistence of ADBAC demonstrated in the aerobic aquatic metabolism study (MRID 40835604).

4.1.3 Water Quality

ADBAC is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act[9]. In addition, no Total Maximum Daily Loads (TMDL) have been developed for ADBAC[10]. More information on impaired water bodies and TMDLs can be found at EPA's website[11].

4.2 Conceptual Models for Environmental Exposure Pathways

Based on the summary of registered uses of ADBAC presented in Table 6, physical/chemical properties and environmental fate data presented in Table 4 and Appendix B, the Agency has developed conceptual model diagrams for exposure of ecological organisms to ADBAC. Under environmental conditions where ADBAC is likely to be released, ADBAC is not likely to hydrolyze (MRID 40835602). ADBAC is not expected to photolyze in water without a sensitizer (*e.g.*, acetone) present (MRID 40835603).

Chemicals that are released down-the-drain can typically take from a few to several hours to reach wastewater treatment plant intakes following their discharge down-the-drain and from several hours to roughly a day following their discharge to subsequently be discharged from wastewater treatment plants to surface water. Since ADBAC is stable to chemical degradation (hydrolysis and photodegradation), ADBAC is expected to enter wastewater treatment plants as a result of down-the-drain discharges of ADBAC. Sorption to sludge is expected to be the main pathway for removal of ADBAC entering WWTPs but data on this pathway have not been submitted. Because of ADBAC's expected stability in the aquatic environment, aquatic organisms in surface water downstream of both direct and indirect sources of ADBAC would be expected to be exposed to ADBAC and not its degradation products.

[9] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885
[10] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES
[11] http://www.epa.gov/owow/tmdl/

The Agency has created conceptual models for potential routes of environmental exposure which are included in "Conceptual Models for Environmental Exposure Pathways of Antimicrobial Pesticides," found in the docket at www.regulations.gov, EPA-HQ-OPP-2014-0638-0002.

Use sites and corresponding figures of conceptual model diagrams are as follows:

- Cleaning and laundry down-the-drain uses (slide 15)
- Cooling towers and air washer systems (slides 13 and 14)
- Pulp and paper mill use (slide 26)
- Swimming pool and spa use (slides 27 and 28)
- Wood preservative industrial use (slide 29) or professional/amateur in-service use (slides 30 and 31)

For conventional uses (*e.g.* applications to turf and golf courses), ecological receptors that may potentially be exposed to ADBAC include terrestrial and semiaquatic wildlife (*i.e.*, mammals, birds, amphibians and reptiles), terrestrial and semi-aquatic plants, and terrestrial soil and aquatic sediment invertebrates. Additionally, aquatic organisms (*i.e.*, freshwater and estuarine/marine fish and invertebrates, amphibians, and aquatic plants) are potential receptors in adjacent water bodies through the off-site transport of ADBAC from the application site through erosion and spray drift (commercial turf and golf courses). Based on ADBAC's sorption properties, it is not expected that off-site transport via runoff water discharged to surface water will be of concern.

4.3 Ecological Effects Assessment

4.3.1 Ecotoxicity Endpoints

Acute and chronic toxicity data from registrant-submitted studies (850 OCSPP Harmonized Test Guidelines[12]) are used to evaluate the potential effects of the ADBACs to aquatic and terrestrial nontarget organisms. Available ecotoxicity endpoints, data requirements, and data gaps for the ADBACs are presented in Appendix C. OPP uses the most sensitive of these endpoints for assessing risks to each receptor group. The endpoints currently available for risk assessment are listed in Table 30.

On an acute exposure basis, ADBAC is highly toxic to freshwater and marine/estuarine fish and freshwater invertebrates. Freshwater invertebrates are especially sensitive to ABDAC on an acute exposure basis, as the acute toxicity classification for ABDAC is very highly toxic (Appendix C). On a chronic exposure basis, freshwater invertebrates are also very sensitive to ABDAC (Appendix C). Chronic data for marine/estuarine invertebrates are expected to be needed, as well as data for aquatic and terrestrial plants (Table 14). These data are needed to support the conventional uses of ABDAC which can be used outdoors. ABDAC is moderately toxic to birds on an acute oral exposure basis. Some data on toxicity to birds have not been submitted, and these data are needed to support the conventional uses (850.2100 with a passerine species and 850.2300). Also, due to the physio-chemical properties of ABDAC, sediment toxicity data are needed. Finally, no toxicity data have been submitted for beneficial insects, and

[12] https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances

these data are needed to understand the potential risk to beneficial insects from the conventional uses.

Table 30 – Existing Ecotoxicity Endpoints

Receptor Group	Test Material	Exposure Scenario	Toxicity Endpoint	Reference (MRID)
Freshwater fish	TGAI	Acute	LC_{50} = 280 µg ai/L	43740103
		Chronic	NOAEC = 32.2 µg ai/L	42302102
Freshwater invertebrates	TGAI	Acute	EC_{50} = 5.9 µg ai/L	41947203
		Chronic	NOAEC = 4.15 µg ai/L	42302101
Estuarine/marine fish	TGAI	Acute	LC_{50} = 310 µg ai/L	Dobbs et al. 1995
Estuarine/marine invertebrates	TGAI	Acute	EC_{50} = 55 µg ai/L	42479503
Freshwater benthic invertebrates[1]	TGAI	Chronic	NOAEC = 520 mg ai/L sediment	43731101
Estuarine/marine benthic invertebrates	TGAI	Chronic	Data gap	--
Aquatic plants (vascular)	TGAI	Aquatic Plants Toxicity (Tiers 1+II)	Data gap	--
Aquatic plants (algal)	TGAI	Algal toxicity (Tiers 1+II)	Data gap	--
Terrestrial Plants	TEP	Seedling Emergence (Tiers 1+II)	Data gap	--
		Vegetative Vigor (Tiers 1+II)	Data gap	--
Birds	TGAI	Acute	LD_{50} = 136 mg ai/kg bw	42885901
		Dietary	LC_{50} =2565 ppm	00119707
Beneficial insects	TGAI	Honey bee adult acute oral	Data gap	--
Beneficial insects	TGAI	Honey bee adult acute contact	Data gap	--
Beneficial insects	TGAI	Honey bee adult chronic oral	Data gap	--
Beneficial insects	TGAI	Honey bee larvae acute oral	Data gap	--
Beneficial insects	TGAI	Honey bee larval chronic larval	Data gap	--
Beneficial insects	TEP	Honey bee toxicity of residues on foliage	Data gap	--

Beneficial insects	TGAI	Semi-field testing for pollinators	Data gap	--
Beneficial insects	TGAI	Field testing for pollinators	Data gap	--

[1] Data are partially satisfied. One additional freshwater species is needed.

4.3.2 Open Literature

The ECOTOXicology (ECOTOX) is a source for locating single chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The database will be searched when the risk assessment is conducted. Any acute or chronic endpoints more sensitive than what is currently available may be used in the risk assessment. Other relevant information also may be used to characterize risks. ECOTOX was created and is maintained by the U.S. EPA, Office of Research and Development (ORD), and the National Health and Environmental Effects Research Laboratory's (NHEERL's) Mid-Continent Ecology Division (MED).
https://cfpub.epa.gov/ecotox/

4.4 Exposure Analysis Plan

4.4.1 Aquatic and Terrestrial Wildlife Exposure Estimates

For antimicrobial uses, if sorption data do not eliminate concerns regarding potential exposures of aquatic organisms to ADBAC, available OPP models will be used to determine estimated environmental concentrations (EECs) in the aquatic environment. Uses of ADBAC expected to result in down-the-drain releases include industrial uses and non-industrial uses, such as residential, commercial, and institutional uses. For the non-industrial uses of ADBAC, such as swimming pools and spas, EPA anticipates the need to use the Down-the-Drain module of Exposure and Fate Assessment Screening Tool (E-FAST), https://www.epa.gov/tsca-screening-tools/exposure-fate-assessment-screening-tool-e-fast-version-20-computer-based, to estimate the number of days of exceedance of concentrations of concern for aquatic organisms downstream of domestic WWTPs. For those industrial uses of ADBAC, such as cooling water systems, air washer systems, and pulp and paper mills that are expected to result in releases down-the-drain to industrial WWTPs, EPA anticipates the need to use the General Population and Ecological Exposure from Industrial Releases module of E-FAST to estimate the number of days of exceedance of concentrations of concern for aquatic organisms downstream of industrial WWTPs. Concentrations of concern for aquatic organisms are based on toxicity endpoints selected to represent each key receptor group, such as freshwater fish, freshwater invertebrates, aquatic plants, estuarine/marine fish, and estuarine/marine invertebrates.

For conventional uses, measures of exposure are based on aquatic and terrestrial models that predict EECs of ADBAC based on maximum labeled application rates and application methods that have the greatest potential for off-site transport of the chemical. The models used to predict aquatic EECs are the Pesticide Root Zone Model coupled with the Variable Volume Water Model (PRZM/VVWM). For exposure to sediment dwelling organisms, predicted pore water EECs are generated using PRZM/VVWM.PRZM (v 5.0+, July 2014) and VVWM (v 1.0, June 2014) are simulation models coupled with the graphical user interface, Pesticide in Water

Calculator (v 1.52, May 2016) to generate daily exposures and 1-in-10-year EECs of ADBAC that may occur in surface water bodies adjacent to application sites receiving ADBAC through erosion and spray drift. PRZM simulates pesticide application, movement and transformation on an agricultural field and the resultant pesticide loadings to a receiving water body via runoff, erosion, and spray drift. VVWM simulates the fate of the pesticide and resulting concentrations in the water body. The standard watershed geometry used for ecological pesticide assessments assumes application to a 10-hectare agricultural field that drains into an adjacent 1-hectare water body that is 2 meters deep (20,000 m3 volume) with no outlet. The composite model PRZM/VVWM is used to estimate exposure of aquatic organisms to ADBAC at a location that is expected to be more vulnerable than most locations where a specific crop is crown. Therefore, the resulting exposure estimates are expected to be protective of aquatic wildlife in most locations. Measures of exposure for aquatic species include the 1-in-10-year peak and 1-in-10-year rolling mean concentrations. The 1-in-10-year peak is used for estimating acute exposures of direct effects to aquatic organisms. The 1-in-10-year 60-day mean is used for assessing chronic exposure to fish and aquatic-phase amphibians. The 1-in-10-year 21-day mean is used for assessing aquatic invertebrate chronic exposure.

KABAM (K_{ow} based Aquatic Bioaccumulation Model) v.1.0 is used to estimate potential bioaccumulation of ADBAC in freshwater aquatic food webs and subsequent risks to mammals and birds via consumption of contaminated aquatic prey. At this time, no tool is available in EFED to quantify the bioaccumulation potential of ADBAC in terrestrial food webs.

Exposure estimates for terrestrial animals assumed to be in the target area or in an area exposed to spray drift are derived using the T-REX (Terrestrial Residue Exposure) model (version 1.5.2, June 2013). This model incorporates the Kenaga nomograph, as modified by Fletcher et al. (1994), which is based on a large set of actual field residue data. The upper limit values from the nomograph represent high end residue values from actual field measurements (Hoerger and Kenaga, 1972). The Fletcher et al. (1994) modifications to the Kenaga nomograph are based on measured field residues from 249 published research papers, including information on 118 species of plants, 121 pesticides, and 17 chemical classes. Given that no suitable data on interception and subsequent dissipation from foliar surfaces are available for ABDAC, the EFED default foliar dissipation half-life of 35 days is used based on high-end dissipation values for pesticides reported by Willis and McDowell (1987).

EECs for terrestrial plants inhabiting dry and wetland areas are derived using TerrPlant (version 1.2.2, October 2009). This model estimates exposure by calculating residues in runoff and in spray drift. These calculations are solely based upon inputs of solubility, application rate, and minimum incorporation depth.

The AgDRIFT spray drift model (v2.1.1; December 2011) is used to assess exposures of organisms to ADBAC that is deposited on terrestrial habitats by spray drift.

Tier I EECs for contact and dietary routes of exposure for foliar and soil applications for honey bees (*Apis mellifera*) are calculated using the Bee-REX model (version 1.0, October 2015). The Tier I method is intended to generate “reasonably conservative” estimates of pesticide exposure to honey bees, where reliable residue values (i.e., measured residue levels in pollen and/or

nectar) are not available. Nectar is considered the major food source for foraging honey bees as well as nurse bees. Therefore, pesticide residues in nectar likely account for most of the exposures to bees, and may represent most of the potential risk concerns for adult bees. However, if residues in pollen are of concern, exposures to nurse bees, which consume more pollen than any other adult honey bees, can be considered. For chemicals with no empirical data to represent the concentration of the chemical in pollen and nectar, dietary exposure for Tier I risk assessment is estimated using generic residue data generated from other chemicals as well as other plant parts. For foliar applications for dietary exposure, it is assumed that pesticide residues on tall grass (from the Kenaga nomogram of T-REX which is incorporated into Bee-REX) are a suitable surrogate for residues in pollen and nectar of flowers that are directly sprayed. For soil applications, pesticide concentrations in pollen and nectar are assumed to be consistent with chemical concentrations in the xylem of barley (calculated using the Briggs' model). More information on Bee-REX and the methodology associated with estimating exposure to honey bees is available at EPA's models website (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#terrestrial).

4.4.2 Screening Level Down-the-Drain Analysis

A screening level Down-the-Drain (DtD) analysis would be performed if all of ADBAC's uses were released from residential, commercial, and institutional applications solely to domestic wastewater treatment plants. However, ADBAC is also used in industrial applications that would lead to discharges to industrial wastewater treatment plants. Therefore, no screening level DtD analysis was performed for this FWP.

5 Endocrine Disruptor Screening Program (EDSP)

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision, for ADBAC, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), ADBAC is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA

will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[13] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[14]

6 Label Changes

As noted in section 1.5, the Agency is actively working to bring ADBAC labels into compliance with risk mitigation measures from the ADBAC RED. ADBAC's PDCIs issued in February and March 2015 required revised labels be submitted according to requirements listed in the RED and Fact Sheet. If the Agency finds that ADBAC's product-specific data and labels are not acceptable, the Agency may require the registrant to submit additional or amended information or proceed with suspension action. The Agency will continue to pursue label compliance through regulatory or other action during registration review, as the RED risk mitigation measures (e.g. Table 7) would impact the scope of ADBAC's risk assessment.

As indicated in Section 1.6.1, the Agency has established tolerance exemptions for residues of some uses of quaternary ammonium compounds in/on food (see Table 8). The end-use concentration of all quaternary chemicals in solution is not to exceed 200 or 400 ppm of active quaternary compound. These exemptions are listed under 40 CFR part 180.940. The Agency notes in Section 3.2.1. that some ADBAC labels allow for end-use solution concentrations for food-contact hard surfaces greater than the established tolerance exemption of 200 or 400 ppm; however, the Agency will use the end-use solution concentrations greater than 400 ppm for risk assessment and will evaluate the need for revisions to the product labels and/or to the existing tolerance exemptions.

The Agency invites any label amendments that could be considered to eliminate the anticipated need for EPA to require certain data, reduce the possibility that EPA's planned risk assessments overestimate risk due to reliance on conservative assumptions, and/or improve label clarity.

[13] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[14] http://www2.epa.gov/endocrine-disruption

7 Next Steps

A DCI will be developed requiring generation and submission of the data listed under the "Anticipated Data Needs" Section of this document. The Agency expects to issue the DCI by March of 2018.

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Appendix A Toxicology Profile

Acute Toxicity for Product Labeling

As listed in Table 16, ADBAC is moderately toxic via the oral, dermal and inhalation routes (Category II). Due to the corrosive nature, the primary eye irritation study was waived and given a category I rating. ADBAC is a dermal irritant (category I) but not a dermal or photo sensitizer.

Table 31 – Acute Toxicity Studies for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC)

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100/ Acute oral toxicity	45109204	=304.5 mg/kg (combined) =510.9 mg/kg (males) =280.8 mg/kg (females)	II
870.1200/ Acute dermal toxicity	45109202	=930 mg/kg (combined) =1100 mg/kg (males) =704 mg/kg (females)	II
870.1300/ Acute inhalation toxicity	44885201	$0.054 < LC_{50} < 0.51$ mg/L	II
870.2400/ Acute eye irritation	waived	-	I
870.2500/ Acute dermal irritation	45109201	Corrosive	I
870.2600/ Skin sensitization	45109203	Not a dermal sensitizer.	NA
Non-guideline/Photosensitization, guinea pigs	40958501 and supplement 44825002	Not a photosensitizer.	NA

N/A=Not available

Subchronic Toxicity

Adequacy of database for Subchronic Toxicity: subchronic toxicity of ADBAC is considered complete. For oral toxicity, the database includes a 90-day oral toxicity test in rats (MRID 40746601). For dermal toxicity, there is a 21-day dermal toxicity study in guinea pigs (MRID 40700700) and a 90-day dermal toxicity study in rats (MRID 41499601). Inhalation was bridged from DDAC (HASPOC memo TXR 0057356).

870.3100 Subchronic (Oral) Toxicity - Rat

In a subchronic oral toxicity study in rats (MRID #40746601), male and female rats were administered ADBAC (79.7% a.i.) in the diet for 13 weeks at dose levels of 0, 100, 500, 1000, 4000, or 8000 ppm. Increased mortality was observed at the 4000 and 8000 ppm dose groups in both sexes. Decreased body weight, weight gain, food consumption and increased incidence of

microscopic lesions [congestion and edema of the G.I. tract, hemorrhaging of the lungs and brain] were also observed in males and females at 4000 ppm. The Systemic NOAEL for males is 500 ppm and for females is 1000 ppm, based upon decreased body weight and weight gain in males at 1000 ppm, and increased mortality, decreased body weight gain and food consumption, and increased microscopic lesions in female rats at 4000 ppm**.** This study is classified as acceptable.

870.3200 Subchronic (21-day dermal) Toxicity – Guinea pig

In a 21-day dermal toxicity study (MRIDs 40565301 and 41105801), a 1:5 dilution of HSsanitizing carpet shampoo (containing 6% didecyl dimethyl ammonium chloride and 4% alkyl dimethyl benzyl ammonium chloride was applied to a 2 inch square area of the shaved dorsal trunk of 5 male and 5 female guinea pigs at doses of 500 and1000 mg/kg, five days a week, for 21 days. There was no mortality or signs of clinical toxicity noted. Signs of skin irritation were noted during the second week of treatment and the report stated that the response intensified during the third week of treatment. Body weight was decreased in treated males and females by 7% and 11% vs untreated animals at week 3 at 1000 mg/kg. Results of hematology and clinical chemistry measurements indicated a slight elevation of basophils and eosinophils as well as a slight elevation of SGPT and SGOT but statistics were not performed on these data. Histologically, the skin irritation was described as a denuded non-vascularized epidermal layer at the application site.

Although this study was identified with several deficiencies (HED document 007757, from the 1/31/90 review by Pamela Hurley, Ph.D.), the data are useful for determining a level of concern for dermal irritation and systemic effects after short-term exposure to ADBAC. In this case, the 500 mg/kg dose level produced no significant dermal or systemic effects, and is considered a NOAEL for the study for dermal irritation and systemic effects.

870.3250 Subchronic (90-day dermal) Toxicity – Rat

In a 90-day dermal toxicity study (MRID 41499601), ADBAC (81.09% a.i.) was applied at dose levels of 0, 2, 6, or 20 mg/kg/day to the clipped backs of Sprague-Dawley rats for 68 hours per day, 5 days per week, for 13 weeks. Although higher doses were tested in a preliminary range-finding study (6, 20, 60, 120, and 200 mg/kg/day), the high dose selected for the main study (20 mg/kg/day) was chosen on the basis that higher concentrations produced skin irritation that was considered greater than slight.

A significant dose related decrease in reticulocyte count was observed in the 6 and 20mg/kg/day females. Decreases in reticulocyte count are normally associated with regenerative responses to anemia. However, no evidence of anemia was seen in other hematological parameters. Furthermore, the decreased levels in treated females were similar to the levels observed in control males. Thus, the decreasing reticulocyte count was most likely not a biologically significant finding.

A significant increase in hyperkeratosis was observed in treated skin of high dose females, but this lesion was also observed in increased incidence in male rats at all doses including controls.

The NOAEL for dermal effects and the NOAEL for systemic effects were 20 mg/kg/day.

TG412 Subchronic (28-day inhalation) Toxicity – Rat – DDAC

In a subchronic inhalation toxicity study (MRID 48667903), Didecyl dimethyl ammonium chloride (DDAC) (50.79%, 00503J5) was administered to 5 Sprague-Dawley rats/sex/concentration by dynamic nose-only exposure at concentrations of 0, 0.08, 0.5, and 1.5 mg/m^3 (0.00008, 0.0005, 0.0015 mg/L) for 6 hours/day, 5 days/week for a total of 20 or 21 days depending on necropsy time. There were two additional groups of 5 rats/sex exposed to 0 or 1.5 mg/m^3 which had a 2-week recovery period before necropsy.

No early mortality was observed in any of the dose groups. At all concentrations in males and at the 0.5 and 1.5 mg/m^3 concentrations in females, lower body weight was observed. In males, these body weights were 6.1%, 9.9% and 20.5% lower respectively in males and 4.0% and 8.5% lower respectively in females. This was statistically significant in 1.5 mg/m^3 dosed males. Lower body weight was correlated with statistically significant lower food consumption. In the 1.5 mg/m^3 group, females and males had increased body weight gain during recovery, leading to full resolution of body weight reduction in females and partial resolution in males.

Concentration-related higher lung weights per 100 grams of body weight occurred in the 1.5 mg/m^3 group males and 0.5 and 1.5 mg/m^3 group females. These changes were reversible. Ulceration of the stratified squamous epithelium in the nasal cavity in the 1.5 mg/m^3 group male and females and degeneration of the olfactory epithelium of the nasal cavity in the 0.5 and 1.5 mg/m^3 group males and 1.5 mg/m^3 group females also occurred.

The bronchoalveolar lavage fluid (BALF) analysis indicated that at the high dose (for most measures the only dose examined other than control) that neutrophils and eosinophils increased with a concomitant decrease in macrophages. In males, there was an increase in cell count and total protein across all doses. In females there was a dose-dependent increase in LDH across all doses, while in males there were increases but the size of some standard deviations made determining dose dependence difficult. This increase was consistent with an increase in lung inflammation. Statistical significance was difficult to assess with the small sample size of 5 animals per group, but trends towards changes in these parameters was clear.

Ulceration and increase in mucus production was most pronounced in the rostral section of the nasal cavity. DDAC produced ulceration of the nasal vestibule lined with stratified squamous epithelium and increased mucus production. There was also degeneration of the olfactory epithelium along with squamous metaplasia in nasal sections II and III. These regions are especially susceptible to injury, as they represent the most rostral extension of the olfactory epithelium. There were increases in mucus respiratory epithelium in a dose and severity dependent fashion. There were also changes in nasal cavity hemorrhage. These effects generally change in severity with dose.

The LOAEC is 0.08 mg/m^3/day based on increases in relative lung weight (males), changes in LDH, BALF total protein, BALF cell count (males only), increase in mucus in the respiratory epithelium, increase in hemorrhage, increase in mucoid exudate. These effects are observed to

occur in a dose dependent fashion. The changes in BAL fluid are consistent with inflammatory effects in the lung. There was also the start of a trend towards lower body weights in males at this dose. There is no NOAEC established in this study.

The RDDR is 0.298 for Extrathoracic Effects based on the MMAD of 1.5 microns and GSD of 1.83 at the dose of 0.08 mg/m^3 and a rat body weight of 289 gram. The rat body weight is the average of the male and female rats of the 0.08 mg/m^3 dose group at Day 25.

The HEC is 0.018 mg/m^3 for 8 hour daily exposures based on the following**:**
HEC = LOAEC * (6 hours/day Rat Exposure /8 hours/day Human Exposure) * RDDR

These findings and conclusions were made using the available information within the report.

This study was missing histopathology of numerous major organ groups as required by the guideline, including but not limited to heart, thymus, spleen, thyroid, bone, testes and stomach. Although these measurements were not made, per guideline, this study is considered acceptable as this study was designed to examine route specific (primarily respiratory) effects.

The study is well designed and provides scientifically sound information. The study is classified as acceptable.

Developmental Toxicity

Adequacy of database for Prenatal Developmental Toxicity: The database includes 2 developmental studies, one in the rat (range-finding MRID 42645101 and main study MRID 42351501) and another in the rabbit (range-finding MRID 42734401 and main study MRID 42392801).

870.3700a Prenatal Developmental Toxicity (Gavage) Study – Rat

In a dose range-finding study for developmental toxicity in rats (MRID # 42645101), ADBAC (81.09%) was administered at doses of 0, 25, 50, 100, 200, or 400 mg/kg/day to CD rats (5/dose) by oral gavage on gestation days 6 through 15, inclusive. Doses ≥ 200 mg/kg/day resulted in 100% mortality; necropsy findings revealed a distended and change in color of the stomach, and distended intestines filled with mucoid fluid. These dams also exhibited clinical signs including loose feces, perioral wetness and perioral encrustation, ataxia, hypoactivity, urogenital area wetness, and audible respiration. Maternal toxicity observed at 100 mg/kg/day was manifest as significantly increased incidence of perioral wetness. The maternal NOAEL and LOAEL are 50 and 100 mg/kg/day, respectively. The NOAEL for developmental toxicity is 100 mg/kg/day based on no survival of dams at 200 and 400 mg/kg/day.

In a developmental toxicity study in rats (MRID # 42351501), female Sprague-Dawley rats (25/dose) were administered ADBAC (81.09% a.i.) by gavage at doses of 0, 10, 30, and 100 mg/kg on gestation days 6 through 15 inclusive for assessment of developmental toxicity. There was no mortality in maternal animals observed at any dose level. At 100 mg/kg/day, one dam exhibited dehydration, unkempt appearance, loose feces, and perioral wetness. At 30 mg/kg/day,

one dam was noted with perioral wetness, gasping, loose feces, and urine stains. Decreased body weight gain (12-13%) was observed in maternal animals at 30 mg/kg/day during gestation days 6- 15. Food consumption was not consistently affected by treatment. There were no treatment related increases in the incidence of fetal external, visceral, or skeletal abnormalities at any dose level. Based on the results of this study, the Maternal NOAEL is 10 mg/kg/day, and the Maternal LOAEL is 30 mg/kg/day, based on clinical signs and decreased body weight gain. The Developmental toxicity NOAEL is 100 mg/kg/day, and the Developmental toxicity LOAEL is > 100 mg/kg/day. There was no evidence for developmental toxicity of ADBAC in this study. This study is classified as acceptable.

870.3700b Prenatal Developmental Toxicity (Gavage) – Rabbit

In a dose range-finding study for developmental toxicity in rabbits (MRID # 42734401), ADBAC (81.09%) was administered at doses of 0, 1, 3, 10, 30, or 60 mg/kg/day to pregnant New Zealand White rabbits (5/dose) by oral gavage on gestation days 6 through 18. Mortality was observed at doses of 30 and 60 mg/kg/day (2 and 5 does, respectively). Audible respiration was observed at doses greater than or equal to 10 mg/kg/day. At doses greater than or equal to 30 mg/kg/day, clinical signs included hypoactivity, perioral wetness, and labored breathing. At 60 mg/kg/day, clinical signs included paralysis, cold extremities, prostration, slow respiration, emaciation, loose feces, and perioral encrustation. Decreased body weight gain and food consumption were observed at doses greater than or equal to 10 mg/kg/day. Developmental toxicity was not observed at any of the doses tested. The maternal NOAEL for the range-finding study is 3 mg/kg/day and the LOAEL is 10 mg/kg/day, based on clinical signs and reduced body weight gain and food consumption. There was no evidence of developmental toxicity of ADBAC in this study.

In a developmental toxicity study in rabbits (MRID # 42392801), ADBAC (81.09%) was administered at doses of 0, 1, 3, or 9 mg/kg/day to pregnant New Zealand White rabbits 16/dose) by oral gavage on gestation days 6 through 18, inclusive. There was no mortality or abortions at any dose level. Hypoactivity and labored breathing were observed at 9 mg/kg/day in 2 of 15 rabbits. There were no effects on maternal body weight, food consumption, cesarean section observations, or necropsy observations. In offspring, there was no evidence of developmental toxicity at any dose level tested. The Maternal NOAEL is 3 mg/kg/day, and the Developmental NOAEL is 9 mg/kg/day. The Maternal LOAEL is 9 mg/kg/day, based on clinical signs of toxicity, and the Developmental LOAEL is > 9 mg/kg/day. There was no evidence of developmental toxicity of ADBAC in this study. This study is classified as acceptable.

Reproductive Toxicity

Adequacy of database for Reproductive: The database for reproductive toxicity of ADBAC is considered complete. The database includes an acceptable 2-generation reproduction toxicity study in rats, MRID 41385001.

870.3800 Reproduction and Fertility Effects – Rat

In a two-generation reproduction toxicity study in rats (MRID # 41385001), ADBAC (81.09%) was administered in the diet to groups of male and female Sprague-Dawley rats (28/sex/dose) at dose levels of 0, 300, 1000, or 2000 ppm over two generations. After 10 weeks of dietary treatment, F0 parental animals were mated. F1 parental animals were mated after 15 weeks of dietary treatment. Mean compound consumption was 20.7, 68.2, and 134.7 mg/kg/day for F0 males, and 25.5, 81.3, and 164.7 mg/kg/day for F0 females. For the F1 males, mean compound consumption was 19.1, 62.5, and 125.4 mg/kg/day, and 24.8, 78.5, and 157.1 mg/kg/day for F1 females.

There was no treatment-related mortality in parental animals at any dose level, and there were no reported signs of clinical toxicity in parental animals. Although some decrease in body weight was observed in both generations at the top dose, the significant variability observed did not qualify this as a treatment-related effect.

In pups of both generations, mean body weights at the top dose were significantly reduced during lactation and post-weaning periods. There were no adverse effects noted on gestational length, mating, fertility, or other gestational indices.

Based on the results of this study, the Parental NOAEL = 146 mg/kg/day, and the Parental LOAEL > 146 mg/kg/day (highest dose tested). The Developmental/Systemic NOAEL = 65.4/79.9 mg/kg/day (M/F), and the Developmental /Systemic LOAEL = 130.1/160.9 mg/kg/day (M/F), based on reduced pup body weight and weight gain during lactation [doses for both the F0 and F1 pups combined].

This study is classified as acceptable.

Chronic Toxicity

Adequacy of database for Chronic Toxicity: The database for chronic toxicity of ADBAC is considered adequate, including a chronic toxicity study in dogs (MRID 43221101) and a combined chronic oral toxicity/carcinogencity study in rats (MRID 41947501).

870.4100 Chronic Toxicity (Oral) – Dog

In a chronic toxicity study in dogs (MRID 43221101), groups of 4 male and female beagle dogs per group received either 0, 120, 400, or 1200 ppm (0, 3.79, 13.1, or 33.8 mg/kg/day in males and 0, 3.67, 14.6, or 38.6 mg/kg/day in females) alkyl dimethyl benzyl ammonium chloride [ADBAC, 80% a.i.] as a direct dietary admix for one year. Systemic toxicity was observed at 400 ppm and above in female dogs and at 1200 ppm in males as reduced body weight gain (approximately 10% reduction) after 52 weeks of exposure. Food consumption was decreased in the 1200 ppm males and females for the entire study period (approximately 15% reduction in males and 5% reduction in females). Based on the data in this study, the Systemic Toxicity NOAEL was 120 ppm (3.79 mg/kg/day in males, 3.67 mg/kg/day in females) and the LOAEL was 400 ppm (13.1 mg/kg/day in males, 14.6 mg/kg/day in females) based on reduced body weight gain.

870.4300 Chronic Toxicity/ Carcinogenicity (Oral) – Rat

In a chronic toxicity / carcinogenicity study (MRID # 41947501), ADBAC (81% purity) was administered in the diet to groups of male and female Sprague-Dawley rats (50/sex/dose) at dose levels of 0, 300, 1000, and 2000 ppm (nominal doses of 13, 44, and 88 mg/kg/day in males; 17, 57, and 116 mg/kg/day in females) for 104 weeks. Significant decreases in group mean body weight were observed in male rats at the 2000 ppm dose level during weeks 1-26 of the study and then sporadically thereafter. Body weights of high dose female rats were also significantly decreased during weeks 1-60 of the study. Body weight gain was decreased 11% on average in high dose males and 14% in high dose females. There were no significant treatment-related effects on clinical chemistry, hematology, or urinalysis. No treatment-related non neoplastic gross or microscopic lesions were evident in any of the treated groups of rats. There was no evidence of carcinogenicity of ADBAC in this study. The Systemic toxicity NOAEL = 1000 ppm, (44 mg/kg/day [M]; 57 mg/kg/day [F]), and the Systemic toxicity LOAEL = 2000 ppm (88 mg/kg/day [M]; 116 mg/kg/day [F], based on decreased body weight and weight gain. This study is classified as acceptable and satisfies the guideline requirement for a chronic toxicity / carcinogenicity study in rats.

Carcinogenicity

Adequacy of database for Carcinogenicity: The database for the carcinogenicity of ADBAC is considered adequate. The database for carcinogenicity includes the 104 week chronic toxicity/carcinogenicity study in rats (MRID 41947501) described in 4.5 and an additional carcinogenicity study in the mouse (MRID 41765201). Results of both studies showed ADBAC to be negative for carcinogenicity.

870.4200 Carcinogenicity (Oral) – Mouse

In a carcinogenicity study in mice (MRID # 41765201), ADBAC (81% purity) was administered in the diet to male and female CD-1 mice (60 sex/dose) at levels of 0, 100, 500, or 1500 ppm for 78 weeks (nominal doses of 14.9, 73.4 and 229.3 mg/kg/day in males; 17.8, 92.1 and 288.6 mg/kg/day in females). No significant differences in the incidence of mortality were observed in treated animals versus controls. No clinical signs of toxicity were observed at any dose level tested. Significant reductions in group mean body weight were observed at the high dose in male and female mice throughout the treatment period with no significant reduction in food intake. There were no significant treatment-related effects on organ weights, macroscopic, or microscopic pathology in treated mice at any dose level. ADBAC was negative for carcinogenicity in this study. The Systemic LOAEL = 1500 ppm in male and female mice (229.3 / 288.6 mg/kg/day), based on reduced body weight. The Systemic NOAEL = 500 ppm in male and female mice (73.4 / 92.1 mg/kg/day). This study is classified as acceptable and satisfies the guideline requirement for a carcinogenicity study in mice.

Mutagenicity

ADBAC has been tested for mutagenicity in an HGPRT assay in CHO cells for forward mutations (MRID 41012701), an in vivo bone marrow chromosome aberration assay (MRID

40311101, supplemental MRID 43037701), and an unscheduled DNA synthesis assay (MRID 42290802 and 4229080). Results of all of these studies were negative for ADBAC.

Metabolism

Adequacy of database for Metabolism and Pharmacokinetics: Disposition of ADBAC was examined in male and female Sprague-Dawley rats (MRID 40990701, supplemental MRIDs 41087701 and 44783401) following a 10 mg/kg single dose by the oral or intravenous route, following exposure to 100 ppm ADBAC for 14 days in the diet, or after a single oral dose of 50 mg/kg. Ring-labeled test material was used. Following oral administration, from 5-8% of the administered dose was eliminated in urine and 90-98% in feces. No apparent differences in disposition were noted between sexes. Following intravenous administration, males eliminated 31% of the dose in urine and 44% in feces, while females eliminated 21% in urine and 55% in feces following intravenous administration. After oral administration, from 0.03-0.58% of the administered dose was accounted for in tissues. After intravenous administration, tissue residues accounted for 33-36% of the dose and were observed mainly in the carcass. The results of this study indicate that a majority of an administered dose of ADBAC is eliminated in feces and involves biliary excretion.

Other Toxicological Effects

Requirement of immunotoxicity, acute and subchronic toxicity studies were waived (HASPOC memo TXR# 0057356).

Appendix B Environmental Fate

Environmental Fate and Transport Properties of ADBAC

ADBAC is completely soluble in water and, based on the vapor pressure and Henry's Law values (Table 4), is not expected to partition from soil and water into air. ADBAC is stable to hydrolysis at pH values of 5, 7, and 9, stable to photodegradation in pH 7 buffered aqueous solutions, but degraded in water in the presence of a photosensitizer with a half-life of 7.1 days. ADBAC is stable to microbial degradation under aerobic and anaerobic conditions in water and sediment, but was readily biodegradable over time in a WWTP simulation study (MRID 46865601). Data relevant to soil metabolism have not been submitted. Sorption to soil, sediment, and sludge is expected to be the primary route of dissipation based on the fact that this is a quaternary ammonium compound with a positive electrical charge that will sorb to negatively-charged particles. In soil and sediment, ADBAC is expected to be immobile based on the Freundlich K_{ads} values of 5,123 to 32,429 L/kg and K_{oc} values of 640,389 to 6,171,657 L/kg (MRID 40835605 and 42414801) based on the FAO soil mobility classification system[9]. Because of its strong sorption to soils, ADBAC is not expected to leach to ground water or be present in dissolved form in runoff water discharged to surface water. ADBAC, however, is expected to be associated with the eroded sediment that is transported during runoff. Table B1 contains a summary of environmental fate data for ADBAC.

ADBAC has the potential to reach WWTPs from the registered uses, and data on activated sludge sorption isotherm (OCSPP 835.1110) and activated sludge respiration inhibition (OCSPP 850.3300) have not been submitted and are required.

Water and Sediment

Hydrolysis

In an acceptable hydrolysis study (MRID 40835602), ADBAC was essentially stable with half-lives of 150 days at pH 5, 183 days at pH 7, and 379 days at pH 9.

Aqueous Photolysis

In a photodegradation in water study (MRID 40835603), ADBAC was found to be stable to photodegradation in sterile buffer solution at pH 7 at 25^{o}C; however, in a sensitized solution ADBAC degraded with a half-life of 7.1 days. This study was classified as upgradable because an unidentified degradate was found 30 days post treatment; however, the study is not invalidated because ADBAC is expected to sorb strongly to sediment, and photodegradation is not expected to be a significant degradation route. Further, ADBAC does not absorb UV light in the 290-800 nm wavelength (MRID 47398502).

ADBAC is considered stable to photodegradation and the aqueous photolysis data may be used in a risk assessment. No further aqueous photolysis data are anticipated to be required.

Octanol-Water Partition Coefficient and Bioconcentration in Fish

The log K_{ow} of ADBAC is 3.91 (Table 4), which is above the level of concern for potential bioconcentration in fish (>3). However, the submitted bioconcentration in fish study (MRID 41026801) demonstrated limited bioconcentration factors of 33X (edible tissues), 160X (non-edible tissue), and 79X for whole fish. The limited bioconcentration is consistent with miscibility of ADBAC in water (Table 4). No additional data are anticipated to be required for bioconcentration in fish.

Aerobic Aquatic Metabolism

In an acceptable aerobic aquatic metabolism study (MRID 40835604), ADBAC showed no degradation during the 30 day study and is classified as stable.

Anaerobic Aquatic Metabolism

In an acceptable anaerobic aquatic metabolism study (MRIDs 41105501 and 42415101), the half-life of ADBAC was determined to be 1,815 days; ADBAC is considered stable.

Leachability from Treated Wood

Wood leaching data were not submitted for ADBAC, but based on the structural, chemical, and physical similarities, DDAC leaching data were used as a surrogate. The leaching rates for DDAC were essentially proportional to the treatment rate of the cubes. The maximum, minimum, and average leaching rates ranged from 1,219-13,330, 104-497, and 348-3,737 ug/cm^2/day at 0.8-3.2 % w/w. The total amount of DDAC leached ranged from 2.6-8.2 % (MRID 49812403). The Agency anticipates similar leaching rates for ADBAC.

Soil

Soil Leaching Adsorption/Desorption Batch Equilibrium

ADBAC had Freundlich K_{ads} value range from 5,123 – 32,429 L/kg and $K_{oc\ values}$ of 640,389 – 6,171,657 L/kg (MRID 40835605 and 42414801). ADBAC is expected to be immobile based on its Freundlich K_{ads} and K_{oc} values[2]. Additional soil leaching data are not anticipated to be required.

Aerobic/Anaerobic Soil Metabolism

No soil metabolism data are anticipated to be required for antimicrobial uses; however, soil metabolism data are anticipated to be required for conventional uses. The data will allow EPA to evaluate potential aquatic exposure of ADBAC and its degradates via runoff from soil erosion after ADBAC has been applied to lawns, turf, and golf courses.

Fate and Transport in WWTP

Activated Sludge Respiration Inhibition

ASRI data are anticipated to be required because the registered uses of ADBAC can result in exposure to microorganisms in WWTPs.

Activated Sludge Biodegradation

In a ready biodegradability study (MRID 46865601), ADBAC was reported to be readily biodegradable based on 10% of the theoretical maximum quantity of CO_2 ($ThCO_2$) formation by 6 days and >60 % of $ThCO_2$ before day 13 (within 10-day window). The study results indicated that ADBAC biodegradation reached 95.5% after 28 days. This study, however, was classified as upgradable rather than acceptable because it did not contain some key information that would allow the Agency to verify these results.

The aerobic aquatic metabolism study results indicated that ADBAC is stable and did not degrade over a 30-day period. Because of the stability indicated by the aerobic aquatic metabolism study, ADBAC would be expected to be resistant to biodegradation during and following wastewater treatment. This contradicts the results of the ready biodegradability study which indicated 10% removal by day 6 and 60% removal by day 13. A possible reason for these results is the interaction between ADBAC and sediment. ADBAC sorbed strongly to the sediment present in the aquatic metabolism study, resulting in stabilization of ADBAC. In the ready biodegradability study, sediment was not present; therefore, ADBAC was available to the microbes during biodegradation.

Activated Sludge Sorption Isotherm

The results of the adsorption/desorption study indicate that ADBAC has a high potential to sorb in a wide range of environmental conditions. No data are available; however, on the potential for ADBAC to sorb during wastewater treatment. ASSI data are anticipated to be required because the registered uses of ADBAC can result in releases to WWTPs, the log K_{ow} value is ≥3. Results of the adsorption/desorption study indicate high sorption potential, and ADBAC is a quaternary ammonium compound that is expected to sorb to sludge because of its positive electrical charge.

If the ASSI study does not demonstrate a strong potential to sorb during activated sludge treatment, the Agency may require verification of results from the ready biodegradability study (MRID 46865601) or an appropriate WWTP biodegradability study as determined by the results of the ASRI test.

Table B1. Environmental Fate Properties of ADBAC

Guideline No.	Parameter	ADBAC	MRID
Leaching-Adsorption/Desorption			
835.1240	K_f/K_{oc} (L/kg) (sand, silt loam, sandy loam, clay loam)	K_f (K_{oc}) 6,172 ($6.2x10^6$), 10,797 ($2.2x10^6$),	40835605 42414801

Guideline No.	Parameter	ADBAC	MRID
		5,123 ($6.4x10^5$), 32,429 ($1.7x10^6$)	
Persistence in Water (half-life)			
835.2120	Hydrolysis at 25 °C (days) pH 5, pH 7, pH 9	150 d, 183 d, 379 d	40835602
835.2240	Aqueous photolysis at 25 °C (days)	stable	40835603
835.4300	Aerobic aquatic metabolism (days)	Stable (sandy loam)	40835604
835.4400	Anaerobic aquatic metabolism half-life (days)	1,815 d (sandy loam)	41105501
Persistence in WWTP (% removed)			
835.3110	Ready Biodegradability	<10% at 24 hrs, 98.5% at 28 d	46865601

Environmental Fate References for Appendix B

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MRID 42414801. Daly, D. (1988) Soil/Sediment Adsorption-Desorption of Alkyl Dimethyl Benzyl Ammonium Chloride: A Supplement: Lab Project Number: 35716. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 480 p.

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MRID 46865601. Van Dievoet, F.; Bouillon, V. (2005) Biodegradability Test Report According to OECD 301 B - Modified. Project Number: ST49132/01/01. Unpublished study prepared by ADBAC Issues Steering Committee/Joint Venture. 11 p.

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MRID 49740501. Hostetler, K. (2015) Rationale for the Chemical Grouping and Read-Across Principles Applied to the Available Physical/Chemical, Toxicology and Ecotoxicology Datasets of the Structural Analogs ADBAC, DDAC and Related Structures. Unpublished study prepared by ADBAC Issues Steering Committee (AIJV). 11p.

MRID 49812403. Bestari, K. (2001) Determination of the Leachability of Bardac 2280 from Treated Wood. Project Number: 2000/CT/WL/B22. Unpublished study prepared by Centre for Toxicology. 114p.

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Appendix C Ecotoxicology Profile

Toxicity to Terrestrial Animals

Birds

Results of the available acute oral (850.2100) and dietary (850.2200) toxicity studies are provided in Table C1. No additional avian toxicity data are needed for the antimicrobial uses. To support the conventional uses, an avian acute oral toxicity study with a passerine species (850.2100) and avian reproduction toxicity studies on an upland game species and a waterfowl species (850.2300) are anticipated to be required.

Table C1. Acute Oral and Dietary Toxicity of ADBAC to Birds

Species	% ai	Toxicity	Toxicity Category	Status/ MRID
Northern bobwhite (*Colinus virginianus*	81	LD_{50} = 136 mg/kg bw	Moderately toxic	Acceptable 42885901
	80	LD_{50} = 220 mg/kg bw	Moderately toxic	Acceptable 00122144
	80	LC_{50} >2430 ppm	Slightly toxic at most	Supplemental 00104009
	80	LC_{50} =2565 ppm	Slightly toxic	Supplemental 00119707
	80	LC_{50} >5000 ppm	Practically nontoxic	Acceptable 00065213
	5	LC_{50} >5000 ppm	Practically nontoxic	Supplemental 00101864
Mallard (*Anas platyrhynchos*)	80	LD_{50} = 580 mg/kg bw	Slightly toxic	Acceptable 00122145
	80	LC_{50} >5000 ppm	Practically nontoxic	Acceptable 00065212
	80	LC_{50} >5760 ppm	Practically nontoxic	Supplemental 00104008
	80	LC_{50} >4500 ppm	Slightly toxic at most	Supplemental 00119707
	5	LC_{50} >5000 ppm	Practically nontoxic	Supplemental 00101864

Nontarget Insects - Honeybees

For antimicrobial uses, no data are available. Additional data are anticipated to be required to support ADBAC antimicrobial uses as a wood preservative and conventional uses. These data include acute oral toxicity to adult honey bees (non-guideline), acute oral toxicity to larval honey bees (non-guideline) and chronic toxicity to adult honey bees (non-guideline). Higher-tier colony level studies may be required pending the outcome of the screening level assessment using

laboratory-based acute (single dose) and chronic (repeat dose) toxicity studies with adult and larval bees (all with TGAI). These higher-tier studies include field trial of residues in pollen and nectar (850.3030), semi-field testing for pollinators (TGAI) and field testing for pollinators (TGAI). In addition, although the acute contact toxicity to adult honey bees study (850.3020) was submitted, there is still outstanding data that must be submitted.

Terrestrial Plants

No data for terrestrial plants are available for ABDAC. Tier I and Tier II seedling emergence (850.4100 and 850.4225) and vegetative vigor data (850.4150 and 850.4250) with the TEP are anticipated to be required to support the conventional uses.

Toxicity to Aquatic Animals

Freshwater Fish and Invertebrates, Acute

Results of acute testing with cold-water and warm-water freshwater fish (850.1075) and freshwater invertebrates (850.1010) are presented in Table C2. No additional data are anticipated to be required for the antimicrobial or conventional uses.

Table C2. Acute Toxicity of ADBAC to Freshwater Fish and Invertebrates

Species	% ai	96-h LC_{50} (µg /L)	Toxicity Category	Status/ MRID
Fathead minnow (*Pimephales promelas)*	81.9	280	Highly toxic	Supplemental 43740103
	50	390	Highly toxic	Supplemental Dobbs et al. 1995*
	50	980	Highly toxic	Supplemental 00064897
Bluegill sunfish (*Lepomis macrochirus)*	50	320	Highly toxic	Supplemental 00064897
	50	510	Highly toxic	Supplemental 00119694
	95.5	515	Highly toxic	Acceptable 41947201
	80	2710	Moderately toxic	Supplemental 00058836
Rainbow Trout (*Oncorhynchus mykiss)*	95.5	923	Highly toxic	Acceptable 41947202
	50	1010	Moderately toxic	Supplemental Dobbs et al. 1995*
	80	1250	Moderately toxic	Acceptable 00122146
	50	2450	Moderately toxic	Supplemental 00064897

Species	% ai	96-h LC_{50} (µg /L)	Toxicity Category	Status/ MRID
	80	7690	Moderately toxic	Supplemental 00058836
Brown trout (*Salmo trutta*)	50	1950	Moderately toxic	Supplemental 00064897
Channel catfish (*Ictalurus punctatus*)	50	980	Highly toxic	Supplemental 00064897
Brown bullhead *(Ictalurus nebulosus*)	50	1590	Moderately toxic	Supplemental 00064897
Green sunfish (*Lepomis cyanellus*)	50	2250	Moderately toxic	Supplemental 00064897
Redear sunfish (*Lepomis microlophus*)	50	740	Highly toxic	Supplemental 00064897
Smallmouth bass (*Micropterus dolomieui*)	50	1370	Moderately toxic	Supplemental 00064897
Goldfish (*Carassius auratus*)	50	1490	Moderately toxic	Supplemental 00064897
Lake trout (*Salvelinus namaycush*)	50	420	Highly toxic	Supplemental 00064897
Largemouth bass ((*Micropterus salmoides*)	50	1130	Moderately toxic	Supplemental 00064897
Waterflea (*Daphnia magna)*	95.5	5.9	Very highly toxic	Acceptable 41947203
	50	20	Very highly toxic	Supplemental Dobbs et al. 1995*

* Study was reviewed by OPP but not assigned an MRID number.

Estuarine/Marine Organisms, Acute

The available data for estuarine/marine fish (850.1075), bivalves (850.1055), and shrimp (850.1035) are presented in Table C3. No additional data are anticipated to be required for the antimicrobial or conventional uses.

Table C3. Acute Toxicity of ADBAC to Estuarine/Marine Organisms

Species	% ai	96-h LC_{50} (µg /L)	Toxicity Category	Status/ MRID
Sheepshead minnow (*Cyprinodon variegatus*)	80.8	860	Highly toxic	Acceptable 42479502
	50	880	Highly toxic	Supplemental Dobbs et al. 1995*
Inland silverside (*Menidia beryllina*)	50	310	Highly toxic	Supplemental Dobbs et al. 1995*
Eastern oyster (*Crassostrea virginica*)	80.8	55	Very highly toxic	Supplemental 42479503

Species	% ai	96-h LC_{50} (µg /L)	Toxicity Category	Status/ MRID
Mysid shrimp (*Mysidopsis bahia)*	80.8	92	Very highly toxic	Acceptable 42479501
	50	>170	Not determined	Supplemental Dobbs et al. 1995*
Grass shrimp (*Palaemonetes pugio*)	80	2810	Moderately toxic	Acceptable 00122147
Shore crab (*Pachygrapsus crassipes*)	80	21,600	Slightly toxic	Acceptable 00122148

* Study was reviewed by OPP but not assigned an MRID number.

Aquatic Organisms, Chronic

Chronic toxicity tests are available for freshwater fish (early life stage, 850.1400) and freshwater invertebrate (life cycle, 850.1300) (Table C4). Acute : chronic ratios can be used to estimate the chronic toxicity of the ADBACs to estuarine/marine fish and invertebrates. No additional testing are anticipated to be required for the antimicrobial or the conventional uses.

Table C4. Chronic Toxicity of ADBAC to Freshwater Organisms

Species	% Active Ingredient	NOAEC and LOAEC (µg /L)	Status/ MRID
Fathead Minnow (*Pimephales promelas*)	30	NOAEC = 32.2 LOAEC = 75.9	Acceptable 42302102
Waterflea (*Daphnia magna*)	30	NOAEC = 4.15 LOAEC = not determined	Supplemental 42302101

Benthic Invertebrates, Chronic

ADBACs have a strong tendency to bind to sediment/soil (K_{ads} >5000, K_{oc} >600,000) and chronic exposure to benthic invertebrates is expected. One chronic sediment toxicity study (no guideline no.) is available for the midge (Table C5). This study partially fulfills the need for chronic sediment testing for freshwater species. To support the antimicrobial and conventional uses, chronic studies also are anticipated to be required for a freshwater amphipod (*i.e., Hyalella azteca*) and an estuarine/marine amphipod (*i.e., Leptocheirus plumulosus*).

Table C5. Chronic Toxicity of Sediment-Incorporated ADBAC to Freshwater Invertebrates

Species	% ai	Endpoints (mg/kg sediment)	Status/ MRID
Midge (*Chironomus tentans*)	80	28-d NOAEC = 520 28-d LOAEC = 1200 14-d LC50 = 548	Supplemental 43731101

Toxicity to Aquatic Plants

No valid guideline data (850.4400, 850.4500, and 850.4550) are available. To support the antimicrobial and conventional uses, testing is anticipated to be required with one species of aquatic vascular plant (*Lemna gibba*) and four species of algae and cyanobacteria: (1) freshwater green alga, *Selenastrum capricornutum*, (2) marine diatom, *Skeletonema costatum*, (3) freshwater diatom, *Navicula pelliculosa*, and (4) cyanobacteria, *Anabaena flos-aquae*.

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Appendix D Screening Level Down-the-Drain Analysis

No screening level Down-the-Drain (DtD) assessment was performed for this FWP. A rationale is provided in Section 4.4.2.

Citric Acid and Salts
Combined Preliminary Work Plan
and
Proposed Interim Registration Review Decision
Case Number 4024

December 2020

Approved by: _____

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Date: December 1, 2020

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Table of Contents

1 Introduction

This document is the Environmental Protection Agency's (EPA or "the Agency") combined Preliminary Work Plan (PWP) and Proposed Interim Registration Review Decision (PID) for citric acid and salts (PC codes 021801 and 021802), herein referred to as citric acid, and is being issued pursuant to 40 CFR Sections 155.50, 155.56 and 155.58. This document explains what EPA's Office of Pesticide Programs knows about citric acid, noting that no additional data nor further assessments are required, and provides an anticipated timeline for completing citric acid's registration review. It also includes the Agency's Proposed Interim Registration Review Decision for the citric acid case.

The Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at www.epa.gov/pesticide-reevaluation.

The Agency is implementing the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The regulations governing registration review are found in 40 CFR Part 155. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

The Agency may issue, when it determines it to be appropriate, a proposed interim registration review decision before completing a registration review. Among other items, the proposed interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. The EPA has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under ESA § 7(a)(2) is not required.[1] Conversely, the Agency will need to complete endocrine screening for citric acid, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

[1] *Citric Acid Final Registration Review Decision* found at https://www regulations.gov/document?D=EPA-HQ-OPP-2008-0855-0012

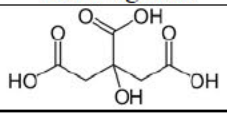
2 Anticipated Data Needs

There are no anticipated data needs to support the registration review for citric acid. As indicated below, during the initial round of registration review, which was concluded on November 20, 2009 with the publication of the *Citric Acid Final Registration Review Decision*, it was decided that no data would be needed and no risk assessment would need to be completed in order to determine that that there are not likely to be any unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, or to non-target organisms or the environment.[2] Consistent with this previous registration review decision, EPA has again decided that no data would be needed, and no updated risk assessment need be completed for this second round of registration review.

3 Citric Acid Chemical Facts

Citric acid chemical facts are shown in Table 1 below.

Table 1 – Chemical Facts for Citric Acid

Chemical Name	Citric Acid and Salts
Chemical Classification	Aliphatic tricarboxylic acid
PC Code	021801
CAS Number	77-92-9
Molecular Formula	$C_6H_8O_7$
Molecular Weight	192.12 g/mol
Molecular Structure	

4 Use/Usage Information

There are 46 EPA-registered antimicrobial products that contain citric acid and salts as an active ingredient, and two products registered for use as herbicides. The percentage active ingredient (a.i.) of the products range from .66% to 66%. The formulations for these products include soluble concentrates and ready-to-use solutions. Certain citric acid products contain only citric acid as the active ingredient, while others are co-formulated with a variety of other active ingredients including sodium chlorite, hydrochloric acid, phosphoric acid, caprylic acid, capric acid, silver ion, sodium dodecylbenzenesulfonate, thymol, alkyl dimethyl benzyl ammonium chloride (ADBAC), didecyldimethylammonium chloride (DDAC), sodium lauryl sulfate, and l-lactic acid.

Citric acid is an antimicrobial pesticide used as a disinfectant, sanitizer, bactericide, fungicide/fungistat, and virucide for hard non-porous surfaces included in many products for use

[2] *Citric Acid Final Registration Review Decision* found at https://www regulations.gov/document?D=EPA-HQ-OPP-2008-0855-0012

in residential and public access premises (e.g. kitchen counter tops, bathroom shower stalls, toilets, utensils, kitchen cutting boards, diaper pails, changing tables, garbage cans, pet area, cafeterias and doctor's offices) and in fruit and vegetable washes for use as a disinfectant, sanitizer, virucide, and germicide. Citric acid is registered in multiple end-use products and is both a food-contact and non-food contact use chemical. In addition, there are over 700 registered products containing citric acid as an inert ingredient. Citric acid is additionally registered for use as a non-selective herbicide. The two currently registered citric acid products, which are co-formulated with acetic acid, are used around residential areas to control grasses and weeds.

5 Regulatory History

The first pesticide products containing citric acid as an active ingredient were registered in the early 1970's. A Reregistration Eligibility Decision (RED) document for citric acid was issued in 1992. In 2006, the Agency implemented the Registration Review program pursuant to FIFRA Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. Pursuant to 40 CFR Sec. 155.50, the Agency formally initiated registration review for citric acid with the following timeline:

- December 2008 – Publication of a *Preliminary Work Plan* (PWP) in the docket for Citric Acid and Salts (EPA-HQ-OPP-2008-0855). During the 90-day comment period that closed on March 17, 2009, the Agency received no comments from the public.
- June 2009 – Issuance of a *Final Work Plan* and *Proposed Registration Review Final Decision* stating that the most recent exposure and risk assessments still support the registration of pesticide products containing citric acid and meet the requirements of registration review. This document also announced the removal of ammonium citrate (or ammonium salts) from the registration review case because ammonium citrate does not have any registered products nor is it being supported by the registrant. Therefore, ammonium citrate was not addressed in registration review case 4024. During the 60-day comment period that closed on August 17, 2009, the Agency received no comments from the public.

This combined Preliminary Work Plan and Proposed Interim Decision marks the beginning of the second cycle of registration review for citric acid and salts, with the opening of public docket EPA-HQ-OPP-2020-0558.

5.1 Tolerance Information

Residues resulting from the use of citric acid when used as either an active or inert ingredient in a pesticide product are exempt from the requirement of a tolerance under 40 CFR 180.950(e), if such use is in accordance with good agricultural or manufacturing practices.

6 Scientific Assessments

A Reregistration Eligibility Decision (RED) document for citric acid was issued in 1992. At that time, all applicable toxicological, ecological and environmental fate requirements were waived. Additionally, during the initial round of registration review, it was decided in the *Citric Acid Final Registration Review Decision* that no data would be needed and no risk assessment would be completed.[3] Consistent with these previous decisions, EPA has again decided that no additional data is needed and no updated risk assessment need be completed for this second round of registration review.

6.1 Human Health Assessment

6.1.1 Hazard Characterization and Risk

Based on the low toxicity of citric acid, the Agency reviewed the hazard and exposure databases and currently anticipates that no additional toxicity and exposure data is needed for this second round of registration review. In addition, the Agency does not anticipate needing any occupational or residential handler assessments in order to ensure that the citric acid registration review case meets the safety standards established by FFDCA, as amended by FQPA. For more human health information on citric acid, please refer to the *Revised Summary of Human Health Effects Data for the Citric Acid Registration Review Decision Document*, dated May 18, 2009 (U.S. EPA, 2009).[4]

Additional toxicity data addressing exposures to citric acid products are not needed for risk assessment purposes at this time due to:

- Citric acid is a compound found in all cells of animal and plant organisms produced and metabolized in the tricarboxylic acid cycle (also called the Krebs cycle).
- The Agency does not have a concern for the inhalation exposures to citric acid as mammalian inhalation studies demonstrate that effects occur at extremely high concentrations of the chemical, concentrations which are not associated with any registered uses.
- Any acute concern from inhalation or dermal exposures is addressed in the label for each product.
- Citric acid has been classified by the U.S. Food and Drug Administration (FDA) as a generally recognized as safe (GRAS) compound without limits.
- Citric acid is used in pharmaceutical and food preparations.

6.1.2 Dietary Exposure Assessment

A dietary risk assessment is not needed for citric acid because exposures of concern are not anticipated. The chemical is a normal part of the metabolism in living organisms as part of the

[3] *Citric Acid Final Registration Review Decision* found at https://www regulations.gov/document?D=EPA-HQ-OPP-2008-0855-0012
[4] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0855

Krebs or citric acid cycle (e.g. part of cellular respiration). The human body contains citrate, most of which is found in bone. Citric acid is widely distributed in plants and animals and is normally present in food in substantial quantities. It is also low in toxicity (tox category III). It is permitted with some conditions as specified in 40 CFR 152.25(f), as both an active and inert ingredient in pesticide products that are exempt from FIFRA regulation under that regulatory exemption. The FDA considers citric acid GRAS for use in foods under 21 CFR 582.1033.

6.1.3 Food Tolerances

Residues resulting from the use of citric acid when used as either an active or inert ingredient in a pesticide product are exempt from the requirement of a tolerance under 40 CFR 180.950(e), if such use is in accordance with good agricultural or manufacturing practices. All uses of citric acid as a disinfectant, sanitizer, bactericide, fungicide/fungistat, and virucide for hard non-porous surfaces in residential and public access premises, and in fruit and vegetable washes for use as a disinfectant, sanitizer, virucide, and germicide are covered under the tolerance exemption, with no specific limits under § 180.950 Tolerance Exemptions for Minimal Risk Active and Inert Ingredients.

6.1.4 Residential and Occupational Exposure Assessment

Because the citric acid RED was completed prior to the advent of FQPA in 1996, a residential assessment was not conducted at that time. Additionally, no other human health assessment was conducted at that time, including an occupational assessment.

Under registration review, an occupational and/or residential exposure assessment is needed for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For citric acid, the toxicological criteria are not triggered. Therefore, consistent with the Agency's prior registration review determination for citric acid in the *Citric Acid Final Registration Review Decision* (2009), the Agency does not anticipate needing new occupational and residential risk assessments for registration review. EPA believes that because of the dilution of citric acid (many labels recommend dilutions as low as 1% active ingredient) in end-use registrations and the existing label requirements, the worker and/or resident is protected from any potential dermal or eye irritation effects identified in the toxicological studies of the technical active ingredient.

6.1.5 Human Health Incidents

Based on a search of the Incident Data System (IDS) for severe incidents (i.e., those classified as deaths or 'major') from 2015 to September 23, 2020, there were no incidents identified that involved only citric acid and salts. EPA typically conducts searches for incident reports inclusive of the past five years, as the Agency considers this timeframe to be the most accurate representation of currently registered use patterns.

6.2 Environmental Risk Assessment

Citric acid is found extensively in nature and is completely biodegradable. It is widely present in plants, animal tissues, and bodily fluids. It is a food-grade substance generally recognized as

safe, non-volatile and relatively inert to aqueous hydrolysis. It is a minimal risk and low concern inert ingredient, a normal component of the human and animal diet, and is an integral part of normal metabolic cycles.

Microorganisms rapidly degrade citric acid in soil and water. Therefore, and again consistent with the Agency's prior registration review determination in the *Citric Acid Final Registration Review Decision* (2009), the Agency does not anticipate needing any environmental fate or ecological effects studies at this time based on citric acid's natural occurrence, common use as a food item, and the lack of significant toxicity and reported adverse effects information. For more environmental fate and ecological information on citric acid, please refer to the *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Citric Acid Registration Review Decision Document* dated November 24, 2008.[5]

6.2.1 Ecological Incidents

Based on a search of the Incident Data System (IDS) for incidents from 2015 to September 23, 2020, there were no incidents identified that involved only citric acid and salts.

6.2.2 Endangered Species Assessment

There is no reasonable expectation for any registered use of citric acid and salts to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of critical habitat is expected from the use of citric acid and salts. This is based on minimal exposure, rapid biodegradability, and low toxicity to non-target organisms, both terrestrial and aquatic. Consistent with the past registration review determination,[6] EPA is making a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under ESA § 7(a)(2) is not required.

6.3 Endocrine Disruptor Screening Program (EDSP)

As required by FIFRA and FFDCA, the EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for chemicals in the citric acid case, the EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as

[5] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2008-0855
[6] *Citric Acid Final Registration Review Decision* found at https://www regulations.gov/document?D=EPA-HQ-OPP-2008-0855-0012

required by FFDCA § 408(p), chemicals in the citric acid case are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,[7] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. The chemicals in the citric acid case are not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit the EPA website.[8]

In this PID, the EPA is making no human health or environmental safety findings associated with the EDSP screening of the chemicals in the citric acid case. Before completing this registration review, the Agency will make an EDSP FFDCA § 408(p) determination.

7 Combined Preliminary Work Plan and Proposed Interim Registration Review Decision

In accordance with 40 CFR Sections 1550.50, 155.56 and 155.58, the Agency is issuing this combined Preliminary Work Plan and Proposed Interim Registration Review Decision document. Except for the EDSP component of the citric acid registration review case, the Agency is proposing that no additional data are required, no further risk assessments are needed, and no label amendments on citric acid products are needed at this time. EPA is making a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species.

[7] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[8] https://www.epa.gov/endocrine-disruption

8 Next Steps and Timeline

A Federal Register Notice will announce the availability of this combined Preliminary Work Plan and Proposed Interim Registration Review Decision for citric acid and allow a 60-day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the Agency to change its decision, EPA may issue an interim decision.

The final decision on the registration review for citric acid (case 4024) will be dependent upon the result of the Agency's EDSP FFDCA § 408(p) determination. See the estimated timeline for the completion of citric acid registration review in Table 2.

Table 2 – Anticipated Combined Preliminary Work Plan and Proposed Interim Registration Review Schedule for Citric Acid

Anticipated Activity	Target Date	Completion Date
Combined Preliminary Work Plan and Proposed Interim Registration Review Decision and Implementation		
Open 60-Day Public Comment Period for Combined Preliminary Work Plan and Proposed Interim Decision	January 2020	
Close Public Comment Period	March 2021	
Issue Interim Decision	June 2021	
Total	6 months	

*The anticipated schedule will be revised as necessary (*e.g.*, need arising under the Endocrine Disruptor Screening Program with respect to the active ingredients in this case).

From: Fugh, Justina

To: Adams, Elizabeth; Amon, Dan; Ankley, Gerald; Aunkst, Dana; Avila, Aaron; Badalamente, Mark; Ballotti, Doug; Barber, Delores; Barmakian, Nancy; Barnet, Henry; Barolo, Mark; Barr, Pamela; Battin, Andrew; Behl, Betsy; Benjamin-Sirmons, Denise; Bergstrand, Paul; Best-Wong, Benita; Binder, Bruce; Birnbaum, Rona; Biro, Susan; Blake, Wendy; Blancato, Jerry; Blevins, John; Bloom, David; Boddu, Veera; Bohan, Suzanne; Bonanno, Gale; Bourbon, John; Breen, Barry; Brennan, Thomas; Brincks, Mike; Briskin, Jeanne; Buckley, Timothy; Buhl, Rick; Bunker, Byron; Burneson, Eric; Busterud, Gretchen; Campbell, Jennie; Canzler, Erica; Caro, Vique; Carpenter, Wesley; Cascio, Wayne; Charmley, William; Cherry, Katrina; Chu, Ed; Clanton, Michael; Clark, Becki; Coleman, Charlotte; Conklin, Jeanne; Coogan, Daniel; Coughlin, Christine; Cozad, David; Crossland, Andy; Crossland, Ronnie; Dalbey, Matthew; Daly, Carl; Dawes, Katherine; Dawson, Jeffrey; DeLeon, Rafael; Diaz-Sanchez, David; Dierker, Carl; Dombrowski, John; Dorka, Lilian; Douchand, Larry; Drake, Kerry; Dufour, Alfred; Dunham, Sarah; Dutton, Steven; Echeverria, Marietta; Edwards, Jonathan; Epley, Brian; Epp, Timothy; Esher, Diana; Eubanks, Kristy; Evangelista, Pat; Fernandez, Cristina; Fine, Steven; Fisher, Bill; Fong, Tera; Frazer, Brian; Freeman, Caroline; Fugh, Justina; Garcia, David; Garland, Jay; George, Elizabeth; Gettle, Jeaneanne; Gillespie, Andrew; Gilliland, Alice; Goodin, John; Goodis, Michael; Goss Eng, Alison; Grantham, Nancy; Gray, Linda; Gray, Richard; Greene, Mary; Grifo, Francesca; Grundler, Christopher; Guerrero, Carmen; Guilaran, Yu-Ting; Guiseppi-Elie, Annette; Gullett, Brian; Gunning, Paul; Gutierrez, Sally; Gwinn, Maureen; Hagler, Gayle; Hamjian, Lynne; Hamlin, Tim; Harris, Michael; Hart, Debbi; Hartman, Mark; Haugen, David; Helm, Arron; Hengst, Benjamin; Henry, Tala; Hill, Randy; Hisel-Mccoy, Sara; Hitchens, Lynnann; Hoff, Dale; Holt, Kay; Hoskinson, Carolyn; Hubbell, Bryan; Huffman, Diane; Hughes, Hayley; Humphrey, Leslie; Hunt, JuanCarlos; Iglesias, Ariel; Jackson, Yvette; Jernberg, Jorianne; Johnson, Arthur; Jones, Samantha; Jones-Peeler, Meshell; Jordan, Deborah; Judson, Richard; Kaczmarek, Chris; Kadeli, Lek; Kamen, Mara; Kaplan, Robert; Kasman, Mark; Keeley, Ann; Keigwin, Richard; Kelley, Rosemarie; Kemker, Carol; Kenny, Shannon; Kloss, Christopher; Knudsen, Thomas; Koerber, Mike; Korleski, Christopher; Koslow, Karin; Kowalski, Edward; LaPosta, Dore; Lassiter, Penny; Lattimore, Kraig; Laureano, Javier; Layne, Arnold; Le, Madison; Lee, Charles; Legare, Pamela; Leonard, Paul; Li, Beverly; Libertz, Catherine; lindsay.nancy@epa.gov; Lloyd, David; Lowery, Brigid; Lowit, Anna; Lupinacci, Jean; Lynch, Mary-Kay; Mackey, Cyndy; Maguire, Charles; Maher, Karen; Manning, Tonya; Martiyan, Stefan; Mathias, Scott; Mathur, Rohit; Matuszko, Jan; May, Benjamin; Mazakas, Pam; McCluney, Lance; McDonald, James; McGartland, Al; McGuire, Karen; McGuire, James; McLain, Jennifer L.; McManus, Catharine; Melvin, Karen; Messina, Edward; Miller, Anthony; Miller, Wynne; Miller, Amy; Monell, Carol; Mooney, John; Moraff, Kenneth; Mosby, Jackie; Mottley, Tanya; Mugdan, Walter; Munns, Wayne; Myrick, Pamela; Nagle, Deborah; Nam, Ed; nesci.kimberly@epa.gov; Neugeboren, Steven; Newton, Cheryl; Nguyen, DucH; Nichols, Tonya; Nickerson, William; Nicolosi, Laura; Noga, Vaughn; OBrien, Kathy; O"Connor, Darcy; Ohanian, Edward; Olson, Bryan; Opalski, Dan; Osinski, Michael; Pace, Donald; Packard, Elise; Palmer, Leif; Patlewicz, Grace; Patrick, Kimberly; Payne, James (Jim); Pease, Anita; Perez, Marc; Peterson, Mary; Pirzadeh, Michelle; Pollins, Mark; Price-Fay, Michelle; Quast, Sylvia; Reaves, Elissa; Reed, Khesha; Richardson, RobinH; Roache, Brendan; Robbins, Chris; Robichaud, Jeffery; Rodan, Bruce; Rodrigues, Cecil; Ross, Mary; Rowson, David; Ruvo, Richard; Salyer, Kathleen; Sams, Reeder; Sanders, Amy; Sasser, Erika; Sasseville, Sonya; Sawyers, Andrew; Sayles, Gregory; Schefski, Kenneth (KC); Scheraga, Joel; Schmidt, Lorie; Scott, Jeff; Scozzafava, MichaelE; Seager, Cheryl; Serassio, Helen; Shah, Imran; Shapiro, Andy; Shaw, Betsy; Sheehan, Charles; Shields, Edward; Simon, Harvey; Simon, Karl; Simon, Nigel; Singh, Amar V.; Singletary, DeAndre; Skelley, Dana; Smidinger, Betsy; Smith, Mark A.; Smith, Charles; Speth, Thomas; Srinivasan, Gautam; Stalcup, Dana; Stanich, Ted; Starfield, Lawrence; Steenbock, John; Stein, Kathie; Stein, Raffael; Strong, Jamie; Szaro, Deb; Talbert-Duarte, Angelia; Tapia, Cecilia; Tapp, Joshua; Taylor, Jessica; Tejada, Matthew; Tellis, Vickie; Terada, Calvin; Terris, Carol; Thayer, Kris; Thomas, Deb; Thomas, Russell; Thompkins, Anita; Thornhill, Alan; Tomiak, Robert; Torres, Tomas; Trimble, Katherine; Tsirigotis, Peter; Updike, David; VanDrunick, Suzanne; Veal, Lee; Viswanathan, Krishna; Vogel, Dana; Wall, Tom; Walsh, Ed; Watkins, Tim; Wayland, Richard; Weber, Rebecca; Wells, Jeffrey; Wells, Krysti; Werner, Jacqueline; Whung, Pai-Yei; Widawsky, David; Williams, Antony; Williams, Maria; Williamson, Anahita; Wood, Anna; Wood, Robert; Wooden-Aguilar, Helena; Wright, Stephanie L.; wyatt.marc@epa.gov; Zapata, Cesar; Zartarian, Valerie; Zepp, Richard

Subject: News about your upcoming financial disclosure filing requirement

Date: Sunday, January 23, 2022 9:06:00 PM

Attachments: Advisory to all 278 filers about filing fee.pdf
When to Report Transactions on the OGE 278 and Part 7 - November 2020.docx

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Hi there,

As you are undoubtedly – and perhaps even painfully -- aware, you are in a position (either acting or permanently) that requires you to file the public financial disclosure report (also known as the 278). This year, we will be assigning your incumbent reports to you *in late February*, so not as early as in previous years. Your due date will be May 16 (because 5/15 is a Sunday), and the reporting period for your incumbent report will be CY 2021 only. But, hey, since I have your attention, allow me to share some important reminders about 278s:

- *Did you know?* EPA was among the first federal agencies to adopt INTEGRITY, the electronic financial disclosure filing system. We've been using it since 2015. Government-wide, there are now more than 35,000 users of this system. At EPA, we typically have more than 250 public filers at any time.

- *Remember about periodic transaction reporting!* You are required to report any transactions of stocks or bonds more than $1000 within 30 days after receiving notice but not later than 45 days after the trade itself. Do so by filing a 278T in INTEGRITY. If you are late, then you are subject to an automatic late filing fee of $200 for missing the deadline. Attached is our reminder about late filing fees as well as a chart about transaction reporting. Alas, last year, we had to fine more than half a dozen people for late transaction filings.
- *Whom should you contact with questions?* Four of us in OGC/Ethics review 278s, so here's the list of contacts for you:

OGC/Ethics	ORGANIZATIONS
Victoria Clarke	OIG, OGC, OMS, OW, Regions 3 and 4
Justina Fugh	AO, OCFO, OITA and Regions 8, 9 and 10
Shannon Griffo	OAR, OCSPP, OECA and Regions 1 and 2
Ferne Mosley	OLEM, ORD and Regions 5, 6 and 7

Thanks for your attention to ethics issues, and we know you're eagerly anticipating the start of the public financial disclosure reporting season later in February!

Cheers,

Justina

Justina Fugh (she/her) | Director, Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
GENERAL COUNSEL

MEMORANDUM

SUBJECT: Timely Filing of Public Financial Disclosure and Periodic Transaction Reports

FROM: David Cozad 8/29/19
Acting Designated Agency Ethics Official

TO: All EPA Public Financial Disclosure Report Filers

In 1978, Congress enacted the Ethics In Government Act, 5 U.S.C. app., to establish the Executive Branch financial disclosure reporting system that requires mandatory public disclosure of financial and employment information of certain officials and their immediate families. Because you occupy a designated position (either permanently or for more than 60 days on detail), you are required by this statute to file the public financial disclosure report. As executive branch employees, we are all bound by federal ethics laws and regulations, including prohibitions against financial conflicts of interest and loss of impartiality. Your disclosures allow the Office of General Counsel's Ethics Office (OGC/Ethics) to assist you in identifying and addressing potential or actual conflicts of interest in order to maintain the integrity of the Agency's programs and operations.

This memorandum formally reminds you that you are required by law to timely and accurately file your Public Financial Disclosure Reports (OGE 278e)[1] and Periodic Transaction Reports (OGE 278-Ts).[2] Failure to file timely will result in a **$200 late filing fee** unless you formally request and receive a waiver of the late fee from the Designated Agency Ethics Official (DAEO) or Alternate Designated Agency Ethics Official (ADAEO).[3] Unpaid late fees are subject to the Agency's[4] and the government's debt collection procedures.

In addition to filing timely, you must also file a complete and accurate report. Should OGC/Ethics contact you for any additional required information, you will have no more than **30 days** to update your report. For guidance on how to file an accurate report, please refer to the Public Financial Disclosure Guide or contact OGE/Ethics at ethics@epa.gov.

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[1] *See* 5 U.S.C. app. § 101; 5 C.F.R. § 2634.201.
[2] Pub. L. 112-105 § 11 (STOCK Act).
[3] *See* 5 U.S.C. app. § 104(d)(1); 5 C.F.R. § 2634.704(a).
[4] *See* Resource Management Directive System 2540-03-P2 dated 07/12/2016.

Please refer to this chart for your filing obligations:

OGE 278e - New Entrant reports	**Within 30 days** of entering a covered position (either by appointment to a permanent or acting in covered position)
OGE 278e – Incumbent reports	**No later than May 15**
OGE 278e – Termination reports	**No later than 30 days after** leaving a covered position (either through reassignment, resignation, or the end of acting in a covered position) (Reports may be submitted within 15 days prior to termination)
OGE 278T – Periodic transaction reports[5]	**The *earlier of* 30 days** after learning of a transaction or **45 days** of the transaction taking place.

How to request an extension of the filing deadline:

For good cause (e.g., travel, workload issues, sickness), you may request up to two 45-day extensions. Submit the request by email, including the reason, to ethics@epa.gov **prior to the due date.** Extensions cannot be granted after the due date has passed.

How to request the waiver of a late filing fee:

If *extraordinary circumstances* prevented you from meeting the deadline and OGC/Ethics assessed a late fee, you may request a waiver of the late fee. *See* 5 C.F.R. § 2634.704. Submit your request in writing to ethics@epa.gov, to the attention of the DAEO and ADAEO, describing the extraordinary circumstances and provide any supporting documentation. Please note that vacations or routine work obligations are not "extraordinary" circumstances. The decision to grant or deny a waiver is at the sole discretion of the DAEO/ADAEO and is final.

You are required by law to comply with these financial reporting obligations. Your colleagues in OGC/Ethics are available to provide assistance, but it is always your obligation to file your reports timely and accurately. In fact, ethics regulations *require* that we refer individuals to the Department of Justice (DOJ) when there is reasonable cause to believe that they have willfully failed to file a required report or provide the information that the report requires. The current maximum civil penalty is $56,216.[6]

As public servants, we know that you take your ethics obligations seriously. As such, we expect you to make a good faith effort to adhere to the timeliness and completeness requirements of your financial disclosure reporting obligations. If you have any questions, please contact ethics@epa.gov.

ATTACHMENT - *When to Report Transactions on the OGE 278 and OGE 278T*

cc: Justina Fugh, Alternate Designated Agency Ethics Official

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[5] *See* attached guidance – *When to Report Transactions on the OGE 278 and OGE 278T.*

[6] In 2012, OGC/Ethics referred an individual to DOJ for failure to file a termination report despite repeated reminders and entreaties. That individual paid a civil penalty of $15,000 and still had to file the termination report.

When to Report Transactions

FILING DEADLINE : 30 days from notification or 45 days from transaction *whichever is earlier*

A $200 late filing fee penalty is assessed for each late periodic reporting period[1]

Investment Assets	Periodic Transaction Report Report on the OGE 278-T?	Annual and/or Termination Report Report on Part 7 of the OGE 278e?
Transactions of $1,000 or less		
• Any asset in which the transaction amount is $1,000 or less regardless of the type of asset or who owns the asset	No	No
Investment assets held by you, your spouse, or jointly held		
• Stocks or stock options	Yes	Yes
• Corporate or municipal bonds (exclude U.S. Treasury securities)	Yes	Yes
• Commodity futures	Yes	Yes
• Other investment securities	Yes	Yes
• Assets listed above in your individual, joint, or spousal brokerage accounts managed accounts, IRAs, other retirement accounts, and/or other investment vehicles	Yes	Yes
Your dependent child's investment assets		
• Stocks	Yes	Yes
• Corporate or municipal bonds (exclude U.S. Treasury securities)	Yes	Yes
• commodity futures	Yes	Yes
• other investment securities	Yes	Yes
• Assets listed above in dependent child's own or UGMA brokerage account, IRAs, and/or other investment vehicles	Yes	Yes
Other investment assets irrespective of ownership		
• Real Property	No	Yes[2]
• Mutual funds, exchange traded funds, 529 plans, index funds, and/or other "excepted investment funds"[3]	No	Yes
• Any asset in which the transaction amount is $1,000 or less	No	No
• Cash accounts (deposits and/or withdrawals) or certificates of deposit	No	No
• Money market accounts and mutual funds	No	No
• US Treasury securities (e.g., T bills, Treasury bonds, savings bonds)	No	No
• Federal government retirement accounts (e.g., Thrift Savings Plan)	No	No
• Life insurance and annuities	No	No
• Collectibles	No	No
• Assets held within an excepted trust[4]	No	No
• Transfer of assets between you, your spouse, and your dependent children	No	No

Last updated November 2020

[1] This late fee is automatically imposed by law and is non-negotiable. You may request a waiver of any late filing fee from the Designated Agency Ethics Official or the Alternate DAEO if there are extraordinary circumstances. A fee waiver is at the sole discretion of the DAEO/ADAEO and is not subject to appeal. A filer who has unpaid late fees will be referred to the appropriate federal office or agency for debt collection procedures.

[2] Do not report the purchase or sale of your personal residence on Part 7 unless you rent it out at any time during the reporting period.

[3] To be an excepted investment fund (EIF), the asset must be:

(a) widely held (more than 100 participants),
(b) independently managed – arranged so that you neither exercise control nor have the ability to exercise control over the financial interests held by the fund, and
(c) publicly traded (or available) or widely diversified.

Managed accounts, investment clubs, trusts, 529 accounts, brokerage accounts, and individual retirement accounts (IRAs) are not excepted investment funds in and of themselves. It may be that individual assets held within these types of investment vehicles may qualify as EIFs if, for example, your IRA holds a publicly-traded mutual fund. But the fact that you have a managed account does not absolve you of your reporting requirements. That account is legally owned by you, and you're responsible for its assets and reporting transactions. If you have questions, contact ethics@epa.gov.

[4] OGC/Ethics must determine that your trust qualifies as an "excepted trust." For help, email ethics@epa.gov.

From: Griffo, Shannon
To: Fugh, Justina
Subject: RE: Anna"s recusal statement - quick question
Date: Monday, August 30, 2021 2:22:00 PM
Attachments: Anna Lowit draft recusal statement 8_30_21.docx

Hi,
I circled back with OPP to ask about (b) (5) [redacted] And as far as registrants, companies who are registered with EPA is available as public knowledge. The Pesticide Product and Labeling System or PPLS (PPLS Website) is a public facing application where users may search products, chemical names, company names, and registrations.
I'm going to leave the company names in the document itself. I accepted your other changes as well. But do we still need that footnote since you added that language into the body of the recusal? Otherwise I think it's good to go to Anna.
Thanks!
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Fugh, Justina <Fugh.Justina@epa.gov>
Sent: Wednesday, August 25, 2021 10:00 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>
Subject: RE: Anna's recusal statement - quick question
Hi,
I mused about this for awhile. See what you think.
Justina
Justina Fugh (she/her) | Director, Ethics Office | Office of General Counsel | US EPA | Mail Code 2311A | Room 4308 North, William Jefferson Clinton Federal Building | Washington, DC 20460 (for ground deliveries, use 20004 for the zip code) | phone 202-564-1786 | fax 202-564-1772

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Wednesday, August 25, 2021 2:39 PM
To: Fugh, Justina <Fugh.Justina@epa.gov>
Subject: Anna's recusal statement - quick question
Hi,
Two quick questions with regards to Anna's recusal statement before I send it to her:

1. I added (b) (5) [redacted] I want your feedback please. (b) (6), (b) (5) [redacted]
2. Look at my comment about (b) (5) [redacted] ?

Thanks!
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Jewell, Shannon
To: Theriault, Alberta (Carla); Griffo, Shannon
Subject: RE: Another question about an OPP public filer
Date: Tuesday, July 27, 2021 1:58:17 PM

Thanks Carla and Shannon!
Shannon

_____

Shannon Jewell · (703) 347-0109 · jewell.shannon@epa.gov

From: Theriault, Alberta (Carla) <Theriault.Carla@epa.gov>
Sent: Tuesday, July 27, 2021 1:55 PM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>; Jewell, Shannon <jewell.shannon@epa.gov>
Subject: RE: Another question about an OPP public filer

Hi Shannon,
We will take a look a the list below and get back to you on what we found.
Many thanks,
Carla

_____

Carla Theriault · (703)-347-8568 · theriault.carla@epa.gov
EPA Office of Pesticide Programs Immediate Office

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Tuesday, July 27, 2021 1:52 PM
To: Jewell, Shannon <jewell.shannon@epa.gov>; Theriault, Alberta (Carla) <Theriault.Carla@epa.gov>
Subject: Another question about an OPP public filer

Hi Shannon and Carla,
I know that Justina reached out about Jan Matuszko (which we will follow up on separately), but now I wanted to check in about another OPP public filer. I'm working with Anna Lowit to update her recusal statement, and wanted to double check whether any of her assets may involve prohibited stocks. Do you mind checking these companies? I think most of them are a no, but here is the list:

(b) (6)
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]
[redacted]

(b) (6)
[redacted]
[redacted]
[redacted]

Thank you!
Shannon
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Griffo, Shannon
To: Theriault, Alberta (Carla); Jewell, Shannon
Subject: RE: Another question about an OPP publ c filer
Date: Tuesday, July 27, 2021 3:16:00 PM
Attachments: image003.jpg
image005.jpg
image007.jpg
image008.jpg

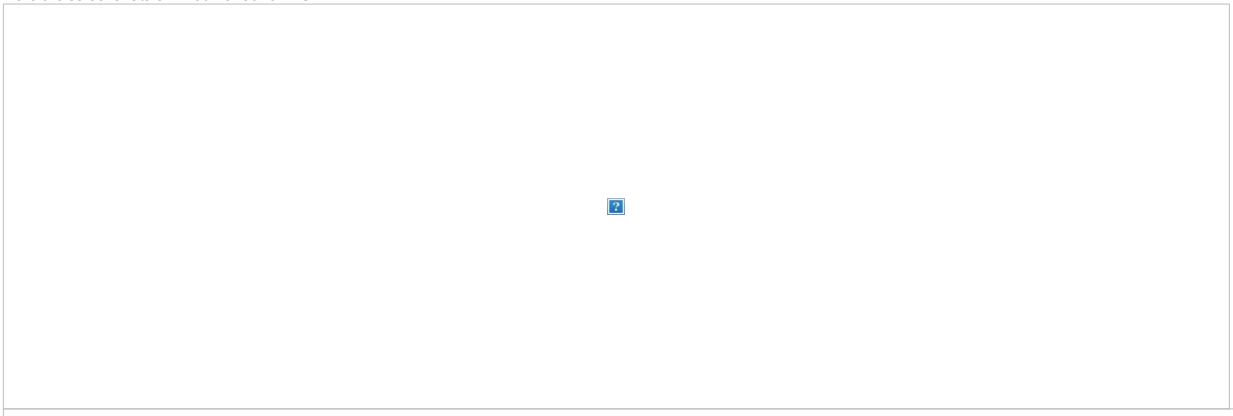
Thanks for the quick review! I ll touch base with Justina and then circle back as needed
Shannon Griffo
Office of General Counsel, Ethics Office
U S Environmental Protection Agency
(202) 564-7061
Griffo Shannon@epa gov

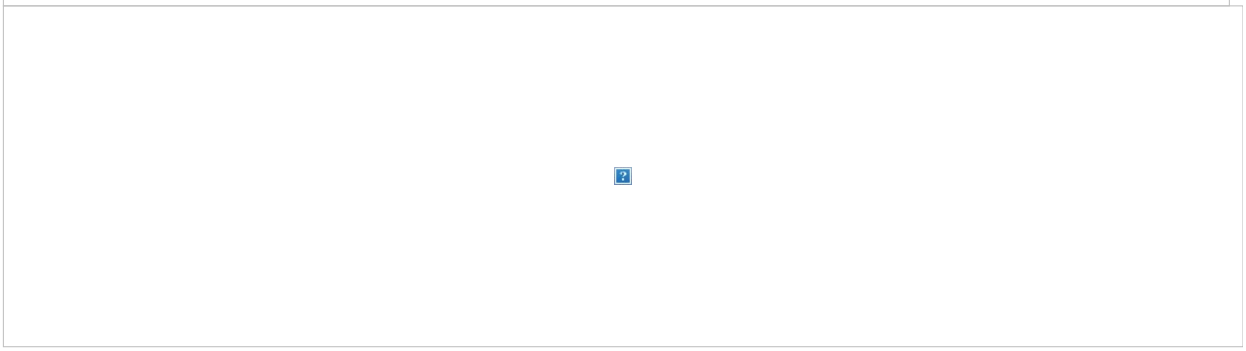
From: Theriault, Alberta (Carla) <Theriault Carla@epa gov>
Sent: Tuesday, July 27, 2021 3 04 PM
To: Griffo, Shannon <Griffo Shannon@epa gov>; Jewell, Shannon <jewell shannon@epa gov>
Subject: RE: Another question about an OPP public filer

Hi Shannon,
I went through the companies below and found 2 that meet the requirements to trigger the supplemental regulation as they have pesticides registered for sale and distribution.
Please let me kow if you have any questions, or need further information

(b) (6)
[redacted]

Here are screenshots of what we found in OPPIN





Many thanks,
Carla

Carla Theriault · (703)-347-8568 · theriault.carla@epa.gov
EPA Office of Pesticide Programs Immediate Office

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Tuesday, July 27, 2021 1:52 PM
To: Jewell, Shannon <jewell.shannon@epa.gov>; Theriault, Alberta (Carla) <Theriault.Carla@epa.gov>
Subject: Another question about an OPP public filer

Hi Shannon and Carla,

I know that Justina reached out about Jan Matuszko (which we will follow up on separately), but now I wanted to check in about another OPP public filer. I'm working with Anna Lowit to update her recusal statement, and wanted to double check whether any of her assets may involve prohibited stocks. Do you mind checking these companies? I think most of them are a no, but here is the list:

(b) (6) [redacted]

Thank you!
Shannon

Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Theriault, Alberta (Carla)
To: Griffo, Shannon; Jewell, Shannon
Subject: RE: Follow-up from OGC/Ethics
Date: Friday, August 13, 2021 4:23:13 PM
Attachments: Lowit cautionary note for 2018 filing.docx
Lowit recusal following 2018 review of 278.docx
Lowit recusal following 2018 review of 278.docx.doc
2019 A. Lowit Recusal.pdf

Hi Shannon,
I wanted to pass these documents along that I found in my searches through Debby's old files. I couldn't find them earlier because the folder was misspelled so my searches didn't yield any results.
Many thanks,
Carla

Carla Theriault · (703)-347-8568 · theriault.carla@epa.gov
EPA Office of Pesticide Programs Immediate Office

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Friday, August 6, 2021 10:15 AM
To: Theriault, Alberta (Carla) <Theriault.Carla@epa.gov>; Jewell, Shannon <jewell.shannon@epa.gov>
Subject: RE: Follow-up from OGC/Ethics
Very helpful. I'll pass this info along to Justina and we will include you both on any meetings we schedule. Have a wonderful weekend!
Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov

From: Theriault, Alberta (Carla) <Theriault.Carla@epa.gov>
Sent: Friday, August 06, 2021 9:24 AM
To: Griffo, Shannon <Griffo.Shannon@epa.gov>; Jewell, Shannon <jewell.shannon@epa.gov>
Subject: RE: Follow-up from OGC/Ethics
Hi Shannon,
I ran a search in Debby's old files and looked at ours and I do not see anything there for either of them. That doesn't mean something couldn't pop up after more digging-it's just what I see right now using their names as search terms.
On Jan's e-450 (b) (6) [redacted]
For Anna, I think she was a public filer last year.
As for attending the meetings with them, I think it would be really benefit me as I am still fairly new to the ethics world and any exposure to things like this greatly helps.
Many thanks,
Carla

Carla Theriault · (703)-347-8568 · theriault.carla@epa.gov

From: Griffo, Shannon <Griffo.Shannon@epa.gov>
Sent: Friday, August 6, 2021 8:41 AM
To: Jewell, Shannon <jewell.shannon@epa.gov>; Theriault, Alberta (Carla) <Theriault.Carla@epa.gov>
Subject: Follow-up from OGC/Ethics

Hi Shannon and Carla,

Thanks for talking with us earlier this week! I'll be out on vacation next week, so I wanted to make sure I checked in before I left about next steps. The first question is whether either of you know if (b) (6) [redacted]). Is there an easy way to check? You don't need to go in the office, and you don't need to ask them. Just wondering if you knew offhand. We will also be reaching out to them to set up separate meetings. And speaking of that, would you both like to attend those meetings? We will chat more about what they work on, their holdings, the supplemental reg etc.

Thanks!

Shannon

Shannon Griffo
Office of General Counsel, Ethics Office
U.S. Environmental Protection Agency
(202) 564-7061
Griffo.Shannon@epa.gov